UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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HHS IMPORTATION TASK FORCE
STAKEHOLDER MEETING

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HEALTH CARE PURCHASERS

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WEDNESDAY
MAY 5, 2004

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The above-entitled matter was held at 10:00 a.m. in Conference Rooms G and H, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland, VADM Richard Carmona, Task Force Chair, presiding.

TASK FORCE MEMBERS PRESENT:

VADM RICHARD CARMONA, Chairman
MR. ALEX M. AZAR, II
MS. JOSEFINA CARBONELL
DR. LESTER M. CRAWFORD
DR. BETTY JAMES DUKE
MS. TRACEY HARDIN
DR. MARK B. McCLELLAN
DR. MIKE O'GRADY
MR. THOMAS REILLY
MR. AMIT K. SACHDEV
DR. ELIZABETH A. WILLIS

PRESENTERS:

Panel 1:
The Honorable Jim Douglas, Governor of Vermont
The Honorable John Hoeven, Governor of North Dakota
The Honorable Tim Pawlenty, Governor of Minnesota
Kevin Concannon, Director, Iowa Dept. of Human Services
(Representing Gov. Tom Vilsack)

Panel 2:
The Honorable John Hurson, Maryland House of Delegates, Vice President, National Conference of State Legislatures
Kurt Knickrehm, Director, Arkansas Department of Human Services, Co-Chair, Health Capacity Task Force, The Council of State Governments
Steven Rowe, Attorney General, State of Maine
(Representing National Association of Attorneys General)
Jim Frogue, Health and Human Services Task Force, American Legislative Exchange Council

Panel 3:
Thomas M. Ryan, Chairman,
President and CEO of CVS/Pharmacy
Thomas S. Paul, Chief Pharmacy Officer for Ovations, UnitedHealth Group
Allen Dunehew, Vice President of Pharmacy for Amerinet, speaking on behalf of the Health Industry Group Purchasing Association

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P R O C E E D I N G S

(10:11:08 a.m.)

SURGEON GENERAL CARMONA: Ladies and gentlemen, could you please take your seats. We'd like to get started. Ladies and gentlemen, good morning and welcome to our task force meeting. Just a few administrative remarks to begin with and then we'll get going.

First, I'd like to personally on behalf of Secretary Thompson thank the Governors and Mr. Concannon representing the Governor of Iowa for taking the time to be with us today. Certainly, your input is extremely important to our deliberations to be able to deliver the Secretary a quality product which is broadly representative of all of the issues, so we can move forward as we look at the issues of policy around drug importation. So Governors, thank you so much for taking the time to be with us.

Ladies and gentlemen, we will follow the schedule that we have been doing over the past several meetings. We'd ask the speakers to be mindful of the clock, if possible to stay within the five minutes that we've allowed all the speakers. At the end of your speaking, we'll move to the next speaker. And at the end of the panel, then the task force will ask any questions it may

have of the panel members. And at the end of this panel, then we'll take a short break and then we'll reconvene after that break and continue with Panel 2.

Once again, I want to thank the Governors. I want to thank all of our other speakers for taking time to be with us today because the quality product that we hope to deliver to the Secretary and then, of course, onto the President and Congress really is going to be dependent upon the diverse input that we receive from all of you.

As I've said repeatedly, and as my colleagues have said, the further we move into this area, we find out just how complex it is. And for every question that's answered, often we have more doors opening with more questions. So once again, thanks very much, and we'll begin now with Governor Jim Douglas of Vermont. Governor, thank you so much.

GOV. DOUGLAS: Well, thank you, Admiral Carmona, for your gracious invitation, and for also taking on this important responsibility. As you indicated, it's a complex one, but an important one for the people of my state, and the American people, and I wish you well in your responsibilities.

I know that you've heard from a lot of people who have talked about how the cost for prescription drugs have risen so sharply in recent years, and a major factor in rising healthcare costs, and that's certainly true in all of our states. These costs burden our families, our businesses, and governments alike. I know that you share my concern and that of my colleagues for the disparity that exists in the global pharmaceutical market, and that's what makes this particular challenge so great.

I guess there are a number of reasons for the inequality, including price controls in other countries that adversely impact the world prescription drug market. But one thing is clear, despite the complexity of the market, Americans aren't getting the lower cost options that they need and that they deserve. Savings available from Canada and other industrialized nations are so substantial, 85 percent less in at least one case, Tamoxifin, that they're impossible to ignore.

The oppressive cost of pharmaceuticals, the rising cost of healthcare, the much publicized disparity of prices may explain why 71 percent of Americans in a recent poll support legalizing prescription drug sales from Canada.

There have been two reasons that I've

heard cited for prohibiting importation of prescription drugs. First, the threat of improperly labeled counterfeit drugs. And secondly, improper handling and storage. They're certainly reasonable concerns, but I think not insurmountable.

Based on all the evidence I've seen, prescription drugs are regulated just as strictly in Canada as they are in the United States. And proper handling and storage of prescription drugs obtained from licensed Canadian pharmacies has never really been challenged. The integrity of the supply system, the distribution system in Canada for drugs equals, if not exceeds, that in our own country. The methods used to ship and deliver drugs from Canadian pharmacies aren't any different from those used by mail-order pharmacies located in our country.

As recently submitted by the Food and Drug Administration in testimony at Congressional hearings, there hasn't been one documented instance of an American citizen being harmed by counterfeit or substandard drugs obtained from a licensed Canadian pharmacy.

As you know, the FDA has consistently followed a policy of intentional non-enforcement of this provision in the case of individual citizens

who obtain a 90-day supply or less of drugs from Canada, so I think the real health and safety issue that we need to address is the inability of thousands of Vermonters and millions of Americans to afford the prescription drugs that they need, and the fact that many of them are simply doing without them. Denying Americans the freedom to obtain medications from a safe, certified, or a licensed pharmacy in Canada just makes the problem worse.

The methods for assuring safety and integrity of the drug supply described in the McCain-Dorgan Bill by a system of inspections and certification or a similar approach advanced by some states and provinces would be adequate protections, in my view.

Short of a nationwide policy allowing for importation, Vermont is prepared to serve as a national model. In fact, we've taken the initial steps by making a Canadian drug purchasing option available within our state employees' healthcare plan for employees, retirees, and their dependents. The ultimate goal, of course, is to get the best deal possible for all Vermonters on their drugs, including pharmacists and wholesalers.

In order to be sure that we remain in compliance with all applicable federal laws while

we work to urge the Congress to act on this important issue, I developed a plan for reimportation and petitioned the FDA for approval of the plan. The basic framework includes the selection of a third-party administrator in Canada to receive prescriptions from Vermonters enrolled in the plan. The third-party administrator would contract with Canadian physicians and accredited pharmacies that would fill the prescriptions and return them to Vermont.

Given our small population and our proximity to the border, approval of our petition would allow Vermont to serve as a model for the rest of the nation. State leaders need to continue to urge this task force and the Congress to address the reimportation issue, and allow the states the flexibility we need to help our residents manage the skyrocketing cost of prescription drugs.

I want to stress, though, that I really think reimportation is not a long-term solution, but rather a way to bring Americans some relief, and a way to pressure for much needed national and international market reforms. It's obvious that America supports the world in terms of research and development costs, and ultimately I hope through freer trade, we can open the markets and get other developed nations to pay their fair share. So

change in the pharmaceutical marketplace I think will come, but Vermonters aren't content to sit around and wait for it to happen. That's why I hope that the task force will urge the administration and the Congress to continue to move expeditiously toward better deals for all Americans.

It's very important that we work as partners, the states and the federal government, to work within the laws of the United States and our respective states, and I pledge to continue to do that.

I want to thank the Department of Health and Human Services and the CMS, in particular, for their recent support for our multi-state purchasing pool that Michigan and other states along with Vermont have organized. It's really important that we do whatever we can to lower the cost of drugs, and your approval of that pool will save us millions of dollars in our Medicaid program, and I know lots of significant savings for these other states, as well. So there are lots of creative ways that we can go about this. That's one. I think allowing reimportation under reasonable standards of safety and security is another. I hope the task force will continue to move in that direction. Thank you.

SURGEON GENERAL CARMONA: Thank you, Governor. Our next speaker, Governor John Hoeven. Thank you, sir.

GOV. HOEVEN: Thank you. I'd like to thank the Surgeon General and the members of the task force for inviting me to be with you today. Prescription drugs play an ever-increasing role in healthcare today, and will continue to as they provide less expensive and less intrusive methods of treating illness. That's why it's so important that we make them available to our citizens on as affordable a basis as possible.

On a federal level, this administration has added a prescription drug benefit to the Medicare Program, a truly historic change for our nation's seniors. It's an addition that I supported, both as a member of the National Governors Association Task Force on Medicaid Reform, and as Chairman of the National Governors Association's Health and Human Services Committee.

In our state governments, we struggle every day to see the benefits of prescription drugs are extended to citizens at prices they can afford to pay. We've looked at a variety of ways to reduce the cost of prescription drugs. In North Dakota, we've established a clearinghouse for the

various discount programs offered by the pharmaceutical companies. We've established prior authorization of drugs within our Medicaid Program. As with most states, we take advantage of buying groups and rebates for our state institutions and for our public employees.

We've now begun the process of contracting pharmacies through the 340B Program, and will utilize the President's Health Center Initiative to the fullest extent in expanding our 340B participation. Each of these measures provides benefits and some relief, but it's limited to certain eligible populations.

In order to give the general public lower cost options when they purchase prescription drugs, we've added several features to our existing programs, and we've incorporated them into a website on the state's portal. The North Dakota prescription drug guide first provides information about generic and therapeutic alternatives that people may consider in place of the brand name drug that they're currently using.

By entering the name of the drug that they're taking, people are directed to a table developed by the North Dakota Pharmaceutical Association that lists generic and therapeutic alternatives. They may then take that list to

their local pharmacist or physician to determine whether an alternative is appropriate for their use given their history and circumstances. That's our first and our preferred option. It saves people the greatest amount of money, and permits them to continue to use their local pharmacist in coordinating their treatment.

We've noted the efforts of AARP to develop evidence-based research of the effectiveness of prescription drugs, and provide it to the public to help them make wiser choices. We applaud the effort, and believe that this additional information will help people make informed decisions about prescription drugs. And it will go hand-in-hand with our effort to get people to talk to their prescribing physician about therapeutic alternatives.

Next, we refer people to the North Dakota Prescription Connection, which is a clearinghouse for the discount programs with counseling available to help people determine their eligibility and apply for applicable programs.

Finally, if neither of those options work, we refer people to Canadian pharmacies. These are pharmacies, in our case in Winnipeg that have been examined and determined to provide safe and reliable service to our citizens.

Living in a border state, North Dakotans are familiar with Canadian towns and cities, and are used to buying a variety of products there, including prescription drugs. In fact, we have farmers that farm on both sides of the border, and our people go back and forth on a regular basis.

Currently, FDA policies and practices allow personal importation of drugs from Canada, but they do not allow the involvement of our local pharmacists, and so many North Dakotans and hundreds of thousands of Americans buy drugs by mail-order over the Internet, but are prohibited from including their pharmacist in their treatment discussions. This should be changed.

Rather than focus on a partial prohibition of the practice of importing drugs from Canada, it would be more beneficial to the safety of patients if FDA would work with Health Canada to reach agreements on the safe importation of prescription drugs. The easiest way to do that would be for the FDA and Health Canada to accept each other's drug approval determinations. People in the United States trust the drug approval and pharmacy practice in Canada. By reaching such agreement, the regulatory agencies of each country could focus on drugs that truly present safety

concern.

Most importantly, approving such importation would allow our pharmacists to fully participate in patient care, and allow our state regulators to license all pharmacies that provide drugs to our citizens, whether those pharmacies are in Manitoba or in North Dakota.

I've urged Secretary Thompson to make the necessary certification before, and I bring the same message today. Help our citizens gain free and complete access to the lower cost drugs in Canada that have proven to be safe and reliable; allow our pharmacists to be part of the treatment team.

Finally, we know that efforts are being made to constrict the Canadian supply of drugs in an attempt to stop importation. Such efforts should not be tolerated, and we support a non-discrimination policy requiring the maintenance of adequate supply.

As a country, we should not be insulated from the world market, left to subsidize the lower cost of prescription drugs given to other countries.

Thank you for inviting me again. I appreciate it, for holding these discussions. I encourage you to move forward, and would be pleased to answer any questions.

SURGEON GENERAL CARMONA: Thank you, Governor. Our next speaker, Governor Tim Pawlenty, of Minnesota. Thank you, sir.

GOV. PAWLENTY: Thank you, Surgeon General Carmona, Dr. McClellan, and members of the task force. Thank you for your diligent work on this issue. I know that this is not easy, it is not simple. It is complicated, and we are hopeful that this esteemed panel with all of your technical expertise and access to the best and the brightest will be able to fashion a good result. We look forward to your work product.

It is a race against the clock, and we appreciate your diligence, and the speed of your meetings, and the diligence of your meetings. As Governor Hoeven mentioned a moment ago, one of the challenges that we have in keeping this effort alive is the drug companies and manufacturers in our country are suffocating supplies to Canada. Our Canadian pharmacies are indicating with respect to some of the most popular drugs, they will be able to continue probably for less than six months, so unless there is some change in policy or behavior at a federal level or with the drug companies, they will succeed in completely or partially suffocating these efforts over the next six months or so.

Many of you probably remember playing the game Red Rover as young children. The refrain of the games is "Red Rover, Red Rover, will you send Jim, or John, or Susie over", and the refrain of the American people with respect to this issue is, to our federal government, to our federal officials, that we please send and allow safe, affordable prescription medicines from Canada to come over.

I think the signs are brewing on Capitol Hill that the debate may be shifting from whether to do this to how to do it. I think you are uniquely positioned to provide the roadmap, the pathway for America to how to do this in a safe and appropriate manner.

I'm not going to rehash the arguments for or against reimportation. They are getting to be well-worn, and I think they're well-known by those of you on the panel. I will say it kind of boils down to safety, since that seems to be the main concern at this point, safety. I don't think the governors here today purport to be technical experts, so we can't guide you or give you great insight with respect to the technical details of this. But I will say our proposal, and it's important to keep in mind, is not to simply have people randomly go out on the internet and deal

with countries that are not as developed as Canada in their pharmaceutical distribution and standards. We are talking about established, licensed, credible, reputable operations in Canada that our federal government or others would certify as such. And as applied to those types of entities, these safety concerns largely melt away, if not entirely melt away.

The thought I would like to leave you with today is this; it is simply implausible, in my opinion, that the United States of America, with all of our innovation, with all of our can-do spirit, with all of our technology is incapable of designing a system whereby we could safely import prescription medicines from Canada. I just simply don't believe that.

This is a country that within the last year or so launched two Rovers to Mars the size of Ford Focuses. They traveled 303 million miles and landed within 2 billionths of 1 percent of their landing zone target. If we could all travel the world and have dinner in a place like Bangkok, and within 28 days Visa has an itemized error-free U.S.A. currency converted statement on your desk at your home.

The Minneapolis Veterans Hospital in Minnesota is a federally-funded, federally-

administered, federally-regulated entity that operates a massive mail-order pharmacy. The logistics and framework for this type of operation exists. Now granted, that's on our distribution and supply chain, but it just has to be expanded legally and geographically.

It is just not plausible to think that this is a country that's incapable of safely importing medicines from Thunder Bay, Ontario to Grand Marais, Minnesota. It's less than an hour away by car. And so, my encouragement to you isn't to offer you technical insights. I trust that you have the expertise and the skill, and access to those kinds of thoughts to put the program together if you want to, but it is a question of setting a goal and getting it done. And when President Kennedy said we're going to go to the moon, people didn't say oh, it's too complicated. We just can't do it. Sorry.

This is a major issue for our country. I hope that you will take a goal-setting approach to it, and try to get it done. I know one of the concerns is perhaps cost. Yes, we could devise a system, but it would be so elaborate and so complex, and so burdensome, and so legal, and so burdened regulatorily that it would just be just unbearable from a cost perspective. I don't know

the answer to that. I hope you can explore it, but again, given modern technology and modern thought, I have a hard time believing we're incapable of putting together this kind of system. So I don't think the question is can we, I think the real question is do we want to? And I want to, and I hope you do too.

Thanks for the chance to come by and share a few thoughts with you. It's an important issue. I don't envy your position. I know it's a difficult issue for a whole lot of reasons, but we genuinely, sincerely appreciate your leadership, and our hope, and our faith, and our trust is in you that you'll come up with a fair and good report. Thank you.

SURGEON GENERAL CARMONA: Thank you, Governor. Our next speaker, Mr. Kevin Concannon, representing Governor Tom Vilsack of Iowa. Thank you, sir.

MR. CONCANNON: Thank you, Surgeon General Carmona, Dr. McClellan, members of the task force. My name is Kevin Concannon. I'm the Director of the Iowa Department of Human Services, and appear before you today representing Governor Tom Vilsack in Iowa.

Iowa strongly favors importation and reimportation of prescription drugs as an

additional way to provide access to needed medications for the residents of our state. Iowa views much greater risks daily to the lives of our residents who should be taking medications for chronic health conditions, but are unable to do so because of the lack of affordability of medications.

In short, we believe there's much greater risk and harm to our residents for this reason, for lack of access primarily due to cost, than the minimal risk associated with importation or reimportation of medications from Canada. We believe the personal safety of our residents is much more seriously compromised each day by their inability to obtain affordable medications than the relatively slight risk of receiving counterfeit medications from Canada.

As a state, Iowa and our administration has proposed to engage in importation and reimportation in a manner that proposes to preserve both the pharmacy home as we know it, just as we support a medical home for the residents of our state. In Iowa, the Iowa Board of Pharmacy Examiners has the authority under state law to license wholesale pharmacy distributors outside the borders of our state. The Iowa Board of Pharmacy Examiners proposes on a pilot basis to work with

our Canadian provincial counterpart regulatory authority to identify single or multiple currently licensed, ethical, experienced wholesale pharmacy distributors to provide sources of medications for state employees, their dependents and retirees in the State of Iowa.

We propose to maintain the pharmacy home in our state by having Iowa residents continue to utilize the pharmacy in their local community by processing prescriptions ordered by Iowa physicians, which are sent to their local pharmacy.

Initially, we propose to limit the importation or reimportation to approximately the 200 most commonly prescribed medications, and on a preliminary basis, the cost differential in acquiring those medications through Canada can both save on the cost of prescription medications, while compensating local Iowa pharmacists for providing professional services for their patients.

We believe steps can be taken to assure the safety of pharmaceutical goods through such a program, and again believe the risk associated with Canadian importation and reimportation have been, and I use this word carefully, hysterically overstated.

For a number of years, I was

responsible for both the Medicaid Program and the Public Health Programs in the State of Maine. Previous to that, in the State of Oregon. Maine has thousands of individuals who have directly or in the mail been obtaining their medications through Canada for many years. I'm pleased to be here today with the Attorney General of the State of Maine, Attorney General Rowe.

Unless things have changed in the last year, we do not have a single example of a problem case of a resident of Maine obtaining their medications from Canada. We believe there are more problems internal to the U.S. mail-order system of prescription drugs. In our view in Iowa, the people unfortunately go without access to medications on a daily basis who should and could otherwise, if they were more affordable.

Experience in Maine in other states that have introduced state supplemental prescription programs have shown that there is a great need for affordable medications for not only senior citizens, but for younger persons, including children who may currently not be receiving those medications, again mainly because of affordability.

Finally, I might point out to the members of this importation task force that Canada, as you probably well know, is not the least

expensive country for medications in the west. Many other western countries pay even less than Canada for medications. There are opportunities for the prescription drug manufacturers to make an adequate profit by expanding affordability and access to additional customers, the patients and their families.

While I would personally favor much broader access across borders for importation and reimportation, at a minimum we urge support for authorizing pilot projects, such as those envisioned in Iowa involving local pharmacies, the Iowa Board of Pharmacy Examiners, state employees, their dependents, and retirees. I thank you for your consideration.

SURGEON GENERAL CARMONA: Thank you, sir. Ladies and gentlemen of the task force, I would like to open the floor to questions for the Governors and for Mr. Concannon. I'll start with Dr. McClellan.

DR. McCLELLAN: I want to thank you all for coming today, and for your passion on addressing the issue of affordable prescription drugs, and also your respect for making sure that the safety issues can be addressed at the same time.

I want to get to some things that we

are doing now to try to address that. Governor Douglas, you mentioned some of these, but I have a question for you first. I had the chance to talk even more extensively to a number of members of Congress about this issue, people who feel passionately in favor of importation like you all do, as part of my confirmation process.

Since that time, a lot of these members are now supporting legislation sponsored by Senator Dorgan, Senator Kennedy, and with a number of co-sponsors that seems to recognize that there are not safety systems in place now to assure that the medicines coming in are legitimate, real medicines from Canada, or from other equivalent approved sources, that they are from pharmacies that are following the same practices for shipments to Americans as the pharmacies in Canada that treat Canadians do, and take other steps to make sure that the drugs coming in are legitimate.

These include, in this Dorgan-Kennedy bill, provisions for registration, inspections, and a new approval process for the FDA. And a lot of people are now debating whether these are processes that are too complex, or whether they get the job done. And we're hearing a lot of views about that on this task force, Governor Pawlenty, exactly as you said. We want to try to sort through that,

figure out whether and how this could be done safely.

I'm wondering, given your perspective on things, do you support that legislation that recognizes that we need a new safety structure for assuring the safety of imports on a large scale?

GOV. DOUGLAS: There's no question that safety has to be the first consideration, and you've spoken eloquently to that, Dr. McClellan. And I think everyone wants to be sure that the pharmaceutical products that come across the international border are safe.

I guess what's difficult for those of us who are from border states, as Governor Hoeven indicated, we don't in many respects regard Canada as a foreign country. We have villages, we have public buildings, we have private homes that are bisected by the international border, and the family ties are historic, and long, and close. And we think nothing of going across the border to shop.

Montreal is our closest big city, and frankly, if the Red Sox don't start doing a little better, we're going to be Expos fans.

(Laughter.)

GOV. DOUGLAS: So we understand the nature of an international border, but believe that

there has to be some way to develop a safety system that's adequate. And as we've noted, the recent record suggests that there have been more problems brought to light within our own country, recent large recall of Lipitor, for example, so obviously, safety has to be first, but I really think that we can find a way.

GOV. HOEVEN: I appreciate your question, Dr. McClellan. Yes, I do support the legislation. There are a number of bills that are in Congress now. You mentioned the bill that's sponsored by Senator Dorgan, but it also has good bipartisan support. I think Senator McCain is on there, Senator Lott, as well as Senator Dorgan and Senator Kennedy, so we're seeing bipartisan support to move forward.

Safety is a primary issue. Again, as Governor Pawlenty testified to, we believe that you can manage the importation safely. I suggested to you that FDA coordinate with Health Canada. And I think in a large regard, you could cover the safety issue working together very well. There may be some exceptions that require additional work, and if so, then you could spend additional time on those exceptions and work with state regulators, as well. But we think it can be done safely, and we think that really the time to move forward is now;

that you have the ability to do it now.

Again, it can be a phased approach where you start with Canada, FDA working in concert with Health Canada. There may be some exceptions, and then you move on from there. But I think it's very, very important that you move forward.

Now according to an AP story that I was reading here just yesterday, last year on the order of a million Americans imported on the order of a billion dollars worth of drugs from Canada. And as Governor Douglas pointed, if you go water skiing in North Dakota, you're going to ski in Canada, as well, on a number of our lakes. It's probably true in Minnesota, as well. And people go in, and whether they go to the McDonald's hamburger joint, or get any kind of candy bar, or any kind of food product, go to the drug store, you know, they go back and forth across the border, and they don't hesitate to go into a pharmacy in Canada and buy prescription drugs, just as they would in the United States.

DR. McCLELLAN: And just to follow up on that, I think I can truly appreciate your perspective and your constituents' perspective about the safety of Canadian pharmacies. I've said many times, as well, when you walk into a Canadian pharmacy that serves Canadians, it's very high-

level assurance, and I think that the bigger concerns are about large-scale purchasing through internet operations and other operations that don't primarily serve Canadians, and where there's at least some questions. And maybe we could talk about this further, too, about whether they're really getting drugs from Canada, where they're following good pharmacy practices, and whether we can make sure there are systems in place to assure that kind of safety.

And while Congress is sorting that out, and they do seem to be more interested - my sense is they're more interested in really coming to terms with those kinds of safety issues, and whether the drugs are really equivalent. This is sort of a question, but also a request - there are a lot of things, as you all said, this is not an either/or choice. There are a lot of strategies that we ought to be pursuing to lower drug costs safely. And many of you have paved the way in a lot of areas beyond the questions of importation.

I guess my request for you, from where I'm sitting now, is that I hope we can work closely together on some of the ways that are proven, and safe, and legal, and available right now. For example, with the new Medicare Drug Card Program, there are, I think, something on the order of

19,000 people in Vermont who would qualify for the $600 in direct assistance, plus additional manufacturer discounts, will get their prescription cost down to $8 for Lipitor. And in Iowa, probably close to 90,000 people; Minnesota over 100,000 people; North Dakota 26,000 people, and then thousands more Medicare beneficiaries who can get the lower prices from the drug cards.

You all have done a great job of setting up outreach programs, websites and the like. I hope we can work together on linking into what we're doing in Medicare to make it as simple and easy as possible for people to find out about these options, and whether it's right for them. Especially for these low-income people who are struggling between drugs and other basic necessities of life. This is thousands of dollars of real assistance right now that we hope we can work together with you to get out there. And for other low-income vulnerable populations, we've got some good programs going now with Governor Douglas. He mentioned the multi-state purchasing pool. I think that's something that Minnesota, I know is interested in pursuing, and you all think you could save $12 million a year by participating in that kind of effort. We want to work with you on that.

There are other proven approaches, like

using generic substitution, programs in Medicaid in your state, health insurance plans. Many states have now tried disease management programs, and we can provide new help to the states in setting these up. These are legal, proven mechanisms that can be implemented right now, so I think there's a lot that can be done, while Congress and others sort out whether and how this can be ?? importation can be done safely through this new kind of regulatory structure to assure safety for the internet pharmacies and the like, so I hope we can try really hard to work together on these other approaches, as well.

We've all got the same goal in the short-term of getting costs down; in the long-term, of getting a fair system for drug pricing around the world that supports innovation, and gives Americans access to affordable medicines. And I sure hope it can be a team effort.

GOV. PAWLENTY: If I might, on the original question that Dr. McClellan raised, the bills that are pending before Congress do speak to the issue of safety, because they built in mechanisms and proposals to address that. And we are mindful of that, and we think that's a good idea. But I think we are, again, not focusing or proposing on some sort of wide open arrangement.

We think that if applied to licensed established, credible, reputable Canadian pharmacies, the record would suggest, the experience would suggest that they are quite safe. And so the challenge isn't to reinvent the wheel, it is how do you then conduct a business relationship with those types of entities, recognizing the internet and mail-order operations all over the globe, even within the United States pretending to be Canadian pharmacies, United States operations, Malaysian operations. There's all kinds of garbage and shady characters operating out there, but that's not what we're proposing. We're proposing that the government, ideally the federal government, use its regulatory and safety powers to credential and establish those kinds of - and identify those kinds of operations and the business protocols around them. And I think the legislation speaks to that, and some would say a couple of them go too far, some would say it doesn't go far enough, but you can light the pathway. This task force can light the pathway for Congress and for the country on how to do this, if you want to.

DR. McCLELLAN: I want to thank you. I'm sorry I have to leave. I've got to go to another event and get some beneficiaries signed up for this low-income assistance right away, but I'm looking forward to working and continuing to work

with all of you on this. It's some very important steps that we're trying to take.

GOV. HOEVEN: Doctor, if I might, just a short comment. You mentioned working together. We want to do that. Still it's very important that you move on this issue, because remember you've got the general population out there that needs to be served, as well. We've got to work on this option from the standpoint of making prescription drugs as affordable as possible to the entire population, so we'll work with you on the specific programs. Again, what we're talking about impacts the entire general population - a very important factor.

GOV. DOUGLAS: Let me also thank Dr. McClellan for keeping this in perspective, and this discussion shouldn't minimize the positive steps we've taken in many other ways. In fact, I'm missing an AARP rally on the steps of our Capitol at noon today to kick-off the Prescription Drug Card Program in Vermont, and there's a lot of potential for savings, and the purchasing pool, we're very grateful for your support and that of the Secretary. But this is a strategy that's important to providing relief to a lot of folks, particularly in Vermont where the average income is barely 80 percent of the national average. It's very expensive. We need to do what we can.

I think in this country, if we agree on the goal, we can find a way.

SURGEON GENERAL CARMONA: Thanks, Mark. Appreciate it. Thank you. Other task force members, questions. Dr. Crawford.

DR. CRAWFORD: Thank you very much. And also, thank you for being here all of you. I appreciated your testimony, made a few notes. There seem to be a couple of key sort of inter-linking issues. One, of course, is cost controls. I think all of you more or less addressed that, and the other is the concern about research and development for the future.

Dealing bilaterally, if you will, on these subjects is not usually successful, so we think in FDA at this point, now that we know that the United Kingdom also wants to join, have the opportunity to export to the U.S. along the same lines, and other countries, no doubt, will step forward - maybe we need some international reference. And there are a couple of organizations that I'd just like to throw out and tell you how we might charge them, and ask what you think.

One is the North American Free Trade Agreement. We have within there the opportunities for this kind of thing to take place. That was certainly contemplated. Maybe that would help with

setting up a system - ask for your reactions to how effective that's been with your states and in the overall situation of dealing with this problem.

The other thing is, on the research and development issue, we now know, it seems like each month the case gets stronger for the United States supporting the research and development enterprise of the world. And we now find that 62 percent of the profitability for the international pharmaceutical community comes from the United States. And that in a very real sense fuels R&D.

Would it be useful, in your view, to go to some organization like the Organization for Economic Cooperation and Development - consists of, as you know, the 40 or so richest countries in the world - and to start an open, free dialogue about how we share the cost of research and development. There may be ways to do it, other than trying to have international price controls.

At the very minimum, in my view, it would raise international consciousness about this. I think working out something quick with Canada, for example, either through legislation or otherwise, might open up the market to other countries standing in the queue to get in, and I think we need a system in place, and maybe that's done by international reference. So I just,

without any malice or whatever, I just throw that out as a possibility, something we worry about at FDA almost as much as we worry about safety.

GOV. PAWLENTY: Dr. Crawford, my initial reaction to that is that it may be well worth pursuing, and may offer some hope, and a more comprehensive approach to the issue. However, it strikes me, in my opinion, that the pharmaceutical industry in our country is in quite a bit of a powerful position, and they're not going to change unless they feel more pressure. And the Canadian solution or option isn't ideal, but it brings pressure. It brings hopefully some increased appetite for change.

I have a very eye-opening experience in Missouri a couple of weeks ago when I went to the Pfizer Board Meeting. The CEO of Pfizer and I talked about trade and how pharmaceutical pricing might be introduced into the discussion about trade. In his press conference when asked having other countries drop price controls or to reform their pricing policies would alleviate price pressures in the United States, his answer was not necessarily. We would perhaps harvest that money for more research and development, and the American consumers shouldn't expect to realize any actual absolute or relative savings. I'm paraphrasing,

but that was the gist of his comments.

I'm also told that in the Australian round of trade negotiations, pharmaceutical pricing has been put on the table for the first time in these types of arrangements, and the goal appears to be from the pharmaceutical industry perspective where they'd like other countries to drop their price structure so they can do to their consumers what they're doing to us. And if that's the net result, if the net result is the pharmaceutical industry then gets to go and have their way so to speak with a country like Australia, I'm not sure that's helpful to our near and intermediate term goals to bring price relief to the American consumer.

MR. CONCANNON: I would add to that. I'm recalling an article written by Dr. Marsha Angel and Reilman, two previous editors of the New England Journal of Medicine back just about a year ago, in which they refuted the oft cited so-called research costs that pharmaceutical industry often invokes. As soon as you start to press your price, we're told that we won't be able to cure Cancer. And I think scientists have looked at that, and again refute some of the so-called costs estimated at bringing a drug to market. But also, I think the industry has changed as we note that often

companies are buying up products that are well-along in the pipeline where they haven't financed the research, so I think I'm not as concerned about the ability of the industry to continue to make it.

It's in their interest to do research, so I'm not as concerned about putting pressure on margins as I am knowledgeable again recognizing that as we sit here today there will be people across the United States who will have strokes, who will have heart attacks, who will die because they don't have access to medications that they should have access to.

GOV. HOEVEN: I think to explore the avenue of looking at some of these trade negotiation settings, maybe something you want to do - I would just caution you though, they typically add significant complexity to the issue, and it's already a very complex issue. We deal with this all the time in our Ag Trade Agreements. We were with the International Trade Commission, U.S. Trade Ambassador's Office, Bo Zoellick and Al Johnson. And we need to move forward on this issue. Our citizens needs this assistance now, and I think what we're suggesting to you is just as you have bilateral trade agreements that advance the process, you have a clear opportunity here to advance the process with Canada. And I do believe

that you can do that within parameters that will allay any concern you might have as regards other countries.

GOV. DOUGLAS: I agree with my colleagues. I think these are ideas worth pursuing, and I hope that we will. As I indicated in my opening remarks, I believe in free trade. I believe that the freedom of markets will ultimately provide some positive pressure on pricing, and we should explore those possibilities.

I also think about the people in my state and others who are earning well below the national average, as I indicated, who have high pharmaceutical costs that they're facing in an improving but still difficult economy, need that relief right away, so I think we should move forward on both fronts; a short-term strategy to provide for reimportation for Canada, and then explore a more comprehensive approach, as well.

SURGEON GENERAL CARMONA: Thank you. Questions from other task force members. Josefina Carbonell.

MS. CARBONELL: I would like to ask following a previous question, would you support the drug importation from Europe?

GOV. PAWLENTY: Ms. Carbonell, I think the easiest and safest route for us right now is

Canada for a whole variety of reasons. I will underscore what I said earlier, there is pretty clear evidence that the pharmaceutical industry is explicitly retaliating against the pharmacies who we've identified and are participating in the program, and they will succeed in suffocating the program within six months, so our options are to shut it down, partially shut it down, or to explore parallel trading or direct trading with the United Kingdom, Switzerland, Scandinavia, other countries that have comparable quality safeguards, sophistication in their drug supply and distribution system. That is not our preference.

I think the American public, as a matter of public relations perception, and as a matter of just relationship comfort feel best about Canada, although I would not rule out, and I'm not going to rule out the possibility of having to explore relationships with Canada-like countries in Europe or elsewhere if the drug industry is successful in suffocating the supply to Canada, so I'm going to leave that option open at least for Minnesota.

MR. CONCANNON: I would be supportive of European importation. I was a number of years a Mental Health Commissioner in several states, three states actually. I recall the nearly miraculous

effects of the drug Clozoril that came from Sandoz Pharmaceuticals at the time, had been available in Europe for a number of years before the U.S., so I'm very conscious of the fact that Lipitor, the most widely prescribed drug now if not in the world, in the U.S., much of it is manufactured in Ireland. We live in a world of global multi-national drug companies.

I think with controls and protections, I certainly would support it.

GOV. HOEVEN: I would agree with the comments that have been made by both gentlemen. I think Canada has offered an option to step forward now, and I think in the legislation that you're going to see from Congress, you are going to be charged with looking at more than Canada. I don't think it's if, I think it's when.

SURGEON GENERAL CARMONA: Thank you. Alex Azar.

MR. AZAR: I wanted to echo what Dr. Carmona and Dr. McClellan have said, thanking all of you for your commitment to lowering the price of drugs in America, and also, Mr. Concannon, it's nice to finally put a face with the name on much litigation. But you've obviously devoted a lot of energy and thought to these issues.

One thing, and I ask this in all

honesty just hoping you can help me think through this - when we talk about importation of drugs from Canada, I think the reason everyone wants to do that is the cost of drugs. And the reason, at least what I've heard so far, that we have a difference in cost of drugs, is that the Canadians have essentially price controls on the drugs there.

It seems like all of the various systems that we end up talking about, alternative safety regimes, control of channels of distribution, regulatory harmonization, that it seems like that ends up being a very complicated and expensive way to skin this cat. Have you all governors thought about imposing, just directly imposing price controls in your state instead of importing ?? going through the Canadian or European importation regime? I'm just trying to figure out why that isn't something that you all have done, or what the factors are that would go into that, considerations.

MR. CONCANNON: I'm not a lawyer, but I have been a frequent defendant, and I think for states to impose price controls on goods that are manufactured in other states gets into ?? creates a constitutional problem.

GOV. PAWLENTY: As a matter of

philosophy, I don't support price controls, and wouldn't pursue that in Minnesota, but I would make two observations in response to your questions. One is, the folks particularly in my political party who say you're just reimporting indirectly the price controls from Canada, and that the net effect of what we're doing is taking advantage of their price controls. I think that's a fair summary.

However, we routinely seek the world for the best price on almost every other commodity without regard to form of government, without regard to regulatory frameworks, without regard to a whole variety of issues. You buy, I bet, all sorts of products from China. People don't stand up and say we can't trade with China. They're Communists. They have diminished human rights expectations. They have labor and environmental policies that are concerning, so why would we single out prescription drugs to get uniquely righteous about with respect to other countries' form of government or regulatory scheme? There's not a good answer to that question, in my view.

Secondly, short of price controls, I think there's a lot more we can and should do as just smart purchasers of prescription medicines in America. It is mystifying to me why the United

States Congress would prohibit itself, prohibit the federal government from allowing to seek a bulk purchase discount for Medicare patients. I mean, I am stunned by that approach. That's not price controls. That's just being a smart purchaser in the marketplace, using the leverage of the bulk ability of the Medicare program to go to the drug companies and say if you want to participate, we expect X percent discount. So short of price controls, there's lots of other things we can and should be doing.

But as to your ultimate question, are we taking advantage of Canada's price controls? You bet, but do we take advantage of every other imperfect form of government around the world on every other product? You bet.

GOV. DOUGLAS: Price controls have certainly been considered in Vermont. In fact, one House of our General Assembly has passed such a measure on a couple of occasions, but I don't expect it to become law. That's why when I originally approach my colleague from Michigan and some others to form the multi-state purchasing pool, we wanted to do it by using the power of the marketplace, not with artificial controls, but by leveraging the volume of our number of lives to negotiate for better prices, so I think that's the

better approach.

GOV. HOEVEN: I guess my response would be, I don't understand why it's up to our government to enforce the price controls of some other country. It doesn't make any sense to me. I mean, if a company in the United States that manufactures prescription drugs is willing to sell drugs into another country at a cheaper price than they're willing to sell it to their own citizens here in our country, why is it up to our federal government to enforce some other country's price controls? It doesn't make sense to me.

MR. AZAR: Wouldn't it be ?? not about enforcing their price controls, but if you want to have price controls in your state, just impose them directly, rather than worry about the issues of safety, and is there trans-shipment through Canada, just if X drug company - you want to sell drugs in our state and not get arrested, you're going to sell it at our price controlled price.

GOV. HOEVEN: I guess if states felt that they could effectively do that, they would be doing it.

SURGEON GENERAL CARMONA: Other questions? Yes, Ms. Willis.

MS. WILLIS: I was wondering if we were able to come to some sort of plan for importation

or reimportation, do you envision that to include all prescription-type drugs, or should there be a restriction on certain types, such as controlled substances?

GOV. PAWLENTY: I think there are all sorts of drugs that should be handled specially or excluded from a program for a whole variety of reasons; they're temperature sensitive, they're the types of narcotics that might be too tempting of a target for interception. In Minnesota, we have limited our program to folks who are on maintenance medicines, and it can't be a prescription of first use. In other words, they have to have already been on the drug, presumably gone through a period of exposure with respect to allergic reaction or the rest, and so we're just allowing maintenance drugs.

So to answer your question, I think there are some drugs that are less well-suited for importation and should be excluded for a variety of reasons. And I might just say, jumping back to Mr. Azar's question - again, reimporting drugs from Canada is not the ideal solution, but we're not picking from ideal options. And it is one way, I think, to reasonably bring some pressure for change on a number of fronts, and I think that is one of the main values of the initiative.

SURGEON GENERAL CARMONA: Thank you, sir. Other questions, comments? Dr. O'Grady.

DR. O'GRADY: Yes. Governor Douglas, I just wanted to talk to you a little bit about this idea of the cross-border trade. And I come from one of those communities that's right on the border, and I can ?? you know, the flip side. Plenty of American entrepreneurs set up large shopping malls and whatnot to draw those Canadian dollars for where our prices are lower. And I certainly understand that dynamic there.

You also brought up that you've tried to incorporate some of these design characteristics in terms of what you're doing for your state employees. And certainly, you've been innovative in terms of the multi-state pools for your Medicaid purchasing. And I guess just as an empirical question, the kind of discounts that you've been able to achieve ?? I mean, one of the things that we have is we see a certain price in Canada, but we know that American consumers are sort of like well, you'll probably get on an airplane later this afternoon, and you know the guy on one side is paying $200 for this ticket, the other guy is paying $6, and you're paying $4. And we know it has to do with that relative ability to, as Governor Pawlenty said, what group you're buying

from, et cetera, et cetera.

In terms of the advantages to the people in your state from doing this, is it that you're trying to get people who aren't kind of ?? access to Medicaid discounts. Is it to bring other people who are either uninsured, or don't have very ?? their insurance companies don't negotiate particularly well for them, to bring them down to that same level, or do you really think that you're going to want to bring large employers in your state, other sort of ?? I mean, are they already there, or close to being there in terms of what you've been able to find?

GOVERNOR DOUGLAS: Well, you make a couple of important points in your question, Dr. O'Grady, that the Medicaid purchasing pool will benefit those beneficiaries, and to a greater extent, the taxpayers of our state through those savings. And our state employee, and retiree and dependent plan helps that population, so there are obviously others who are, as you noted, uninsured. And the percentage of our population who are uninsured has risen dramatically in the last seven years from about 6 to 10 percent of the population. And those who are covered through private insurance plans that may or may not be negotiating for the best deals. So my goal is to extend it to

the entirety of our state's population, especially those who don't have coverage so that they can maintain their supply of needed pharmaceuticals and not impoverish themselves.

And we hear the proverbial stories about people choosing between drugs and food, and that gets to be close to reality in many cases given the relatively low income of the people of our state, and the high cost of drugs. So access to those pharmaceuticals at the lowest possible price is my goal.

DR. O'GRADY: Have you found that in terms of so far what you're finding in terms of people kind of doing the cross-border, that it is more likely to be the sort of folks who are uninsured or have poorer coverage than someone who works for a larger firm, or a state employee?

GOV. DOUGLAS: Generally, I should have said earlier that our state employees' plan is not designed specifically for Canada. We will reimburse a state employee for a drug purchased anywhere in the world. It was designed originally to insure people while traveling and they need drugs, are reimbursed.

We've had a number of well-publicized bus trips of folks going to Canada, mostly seniors. And it will be interesting to see if there's any

change in their attitude because of the new discount card that's available through Medicare, but I would say the majority of people I've seen cross the border have been elderly.

DR. O'GRADY: Thank you. Can I ask one more?

SURGEON GENERAL CARMONA: Please, go ahead. Yes, please.

DR. O'GRADY: Governor Hoeven, as part of your testimony, you brought up this idea of if there's a question of restricted supply to Canada as part of this dynamic, that steps should be taken. I'm just not clear on what those ?? if there's a relationship going on, positive or negative between a private sector company and the Canadian government, or the provincial, you know, the Ontario provincial government, I wasn't quite sure what you had in mind of what steps would be taken by the United States government.

GOV. HOEVEN: The concern, of course, is that supply is being restricted to some of the Canadian internet pharmacies in an effort to prevent personal purchase of prescription drugs from Canada. And I think that we have to make sure that we have fair trade practices in place, and that may be something that would require a legislative approach. Whether you have that from a

regulatory standpoint or not, I don't know, but that's the point I'm making, is that that's a concern.

Again, we're talking about really promoting a citizen's opportunity to buy prescription drugs at the best price. It kind of goes back to the point we were making before. If they can attain prescription drugs safely from Canada, but are precluded from it by our federal government, that's an unfair situation. So you as go forward and address this, what we're saying is you've got to find ways to make that opportunity available to our citizens, either through regulatory means or through legislation.

DR. O'GRADY: Oh, I'm sorry, Governor.

GOV. PAWLENTY: On that point, Dr. O'Grady, originally there was some thought that perhaps there was an anti-trust or could be an anti-trust violation if the pharmaceutical companies were working in concert to choke off supply. Our Attorney General and the Attorney General of some other states have at least explored that possibility by asking for documents. I don't think that's proceeded very far. There's no indication or evidence yet that an anti-trust violation may have occurred.

There are others who speculate that

under current trade laws, the act of punishing a foreign entity for merely engaging in trade or a transaction with a consumer in our country might, or it might violate a trade law. There's some groups who I know who are researching that, and at least considering litigation, but I don't know the particulars. I don't know if it's meritorious, but those are the kinds of theories that are being explored.

DR. O'GRADY: And we have heard from the Canadian government, and kind of the Board of Pharmacists and whatnot, and certainly there's quite a concern on the Canadian side of the border about when they look and all of a sudden see that the shelves are empty, something that there's not really a lot of flexibility. You know, when you're out of insulin, you've got a problem. And so far they've been able to move things around between different pharmacies.

But I'd have to say that the overall tone to a certain degree is not that they're wild about these ideas. And Governor Hoeven, you talked about trying to work something out with Health Canada, and again, do you have something in particular in mind that you could help kind of give us some feel for what those steps would be? As I say, the Canadians do not seem wildly thrilled

about what's going on now, and exactly what effect it's having on their own local markets, and concerns of I think about their own local prices, as well, but I'm putting words in their mouth.

GOV. HOEVEN: Well, in terms of allowing importation, reimportation, and the safety of Canadian prescription drugs, I think there is a high degree of confidence by consumers in both the United States and Canada, clearly in FDA, but also in Health Canada, and so it's kind of the rule versus the exception approach. We think that the vast majority of drugs would fall under essentially the rule, rules that you would agree to between Health Canada and FDA, which would cover most of the drugs that people are importing or reimporting.

There may be some exceptions that either the FDA or Health Canada have concerns about. There may be certain restrictions that they want to apply. Those would be the exceptions, but again, it allows people to move forward in the vast majority of cases. There may be some things that you continue to work on. And that would also extend to drugs that may come into Canada from other countries and those types of things. And I think that goes back to Dr. Crawford's questions about how do you move forward?

You know, the idea is we need to advance because people need this help now, and it is an issue about the general population. Yes, it will help with people that are in groups and so forth, but this is available to the entire population, helps somebody who's uninsured, but also now that FDA is allowing insurance companies to provide reimbursement also helps people that are insured. So it's a way to move forward without solving every single aspect. There may be some things you set off to the side and say this needs more work, but the vast majority of cases are addressed.

GOV. DOUGLAS: Dr. O'Grady, you're not putting words in the Canadian's mouths. I've had this conversation with some of our friends in Quebec, and they are concerned, indeed, about the potential impact on prices there. The explanation I gave them is what I've told the task force today, that this is not the be all and end all to address the cost of pharmaceuticals, but is an important step, at least on an interim basis, that's important for a border state to provide relief from high prices for Vermonters, so they certainly have expressed that concern.

SURGEON GENERAL CARMONA: Dr. Duke.

DR. DUKE: I'd like to address that

issue, because you are a border state. There are a lot of states that are not border states, and we also have another 2,200 mile border with Mexico that is also an area of our nation in which there's a great deal of individual importation. And in my mind, I see that the problem sort of has two aspects; one is the personal importation in the bus heading over to the favorite pharmacy across your border. And we see that both in the north and in the south, southern borders. And then there's the larger issue of a systemic approach to some form of licensing of wholesale purchases on behalf of a general population. And I was hoping you might all comment on that, because I find that in these discussions, often the conversation wanders across this terrain rather loosely, because I see them as two very distinct economic, moral, philosophical, medical issues. And I just hope maybe you would comment on that.

MR. CONCANNON: I'd be happy to comment on it. The Iowa proposal, as I mentioned, as one that we have had direct dialogue with three provincial Canadian pharmacy regulatory boards in the western provinces. And you may already be aware of this, that the price ceiling for prescription drugs in Canada represents a limitation on the median acquisition cost for

medications in something like nine western countries. So Canada doesn't arbitrarily pick a target for Lipitor, Zocor, or something else and say you cannot charge above that. It is the median, the middle price, so that it means that half of those western countries are charging less than that. So I think given that fact, again to me it underscores the fact we're in a global market here.

But back to your question, our proposal - and I heard similar proposals here from one of the governors, or several of the governors, is to at least initially organize this in a way that systematically - not put people at risk, put them up on the internet and say let us know how you make out - but to systematically work with a Canadian regulatory counterpart. As you may be aware, in Canada most of the medications are provided in a blister pack. They don't provide at the retail level medications in the same way we do in the U.S., so that there again I think further protections for people. And we would propose to have those medications go from, again, a selected, ethical, vetted pharmacy wholesaler in Canada that would have to meet our state's standards, as well as provincial standards, have a track record. And then have those medications come back through a

local pharmacy in the U.S.

Why we propose the top 200 medications, again reflects the prescription drug market in the U.S. One of my favorite factoid questions is how many medications does a drug store stock. It's about 2,000, but about half of the prescription drugs spent in the U.S. can be accounted for by the top 200 drugs. So that's why we say we're not going to try to import the 1,950 medications. We're going to limit it to the top 200 drugs.

And again, just as Governor Pawlenty mentioned in his remarks, we don't think this is a perfect solution, but in a world of imperfection, this would help and would be a responsible way to do it systematically, to do it with very minimal risk. And by the way, my impression from meeting with the regulatory agencies in Canada, they are more stringent in terms of their pharmacy regulations than we are in the U.S. They require more stringent reporting at the retail level than we do in the U.S., so I'm not concerned about the Canadian system.

GOV. PAWLENTY: Dr. Duke, I believe one other aspect of your question was by moving from the grandma individual purchase to a commercial level, is that helpful or counterproductive? I think that would actually be helpful, because if

you look at the pharmaceutical or the pharmacy industry in America, it's consolidating. There are certainly many small and independent operators, but if you bring to the table the commercial pharmacies in the form of Wal-Mart and Walgreen's, and CVS and everybody else, you would empower them to be part of the transaction, you would get the benefit of their commercial capabilities, skills, purchasing, due diligence, safety protocols, professionalism. I think it actually would increase the attractiveness of the program from a safety perspective.

GOV. DOUGLAS: I think it has to be comprehensive. I know that Vermont on a map of the United States looks quite small, but it's a four hour drive from some of our southern communities to the international border, and to have those grandmas, and they are grandmas in many cases make that trip, I think is unreasonable, so I hope that we find a way to do it on a comprehensive basis, and provide the safety that's so important.

GOV. HOEVEN: I agree with that. I think that's one of the main points we're making; it needs to be done through the professionals, through the pharmacies so that the citizens have not only the convenience, but the safety of working through the professionals. And that is why it's so

important that you step forward.

GENERAL CARMONA: Thank you, Governors. One last question, I think. You've all, staring with Governor Douglas, either stated or implied that importation doesn't seem to be a long-term solution. It's an imperfect world. We're more or less putting a bandaid on a very complex problem. Be that as it may then, what would you recommend as a long-term solution for our nation?

GOV. DOUGLAS: I think Dr. Crawford offered some suggestions that are helpful to pursue with international partners through agreements and organizations that are in effect now, some greater freedom in the international marketplace. I think free trade can provide some real pressure on a permanent basis to the pricing that we're seeing in pharmaceutical products to allow the rest of the world to share in some of the research and development costs that we're paying here, so I think eventually that's where we should be. But for now, for the folks who need it today, I think reimportation provides an important relief.

GOV. HOEVEN: I think the comment is that starting with Canada is just that, a start; that the longer term solution is for having the safety mechanisms in place, the regulatory structure in place which allows the free trade with

more than just Canada, allows trade with a number of countries.

I think if you ?? the legislation that I think either Surgeon General, you or Dr. McClellan mentioned the bill with Senator Drogan, Senator Kennedy and others, I think that's where it's going. In other words, it's saying we're going to look at a lot of countries, but make sure that we put a structure in place so that we can do it safely. So I think we're saying okay, it's imperfect from the standpoint that we're just starting with Canada, and that's just one step. That's more like a bilateral, but it takes us on the way to a larger and a better solution long-term.

SURGEON GENERAL CARMONA: Thank you.

GOV. PAWLENTY: Surgeon General, I would suggest a few things. One is safe access to world markets, as imperfect as they are, is a helpful tool and point of leverage for the American consumer. That's number one. Number two, I think the Medicare legislation and the prescription drug benefit that will come is a big help, but again it's incomplete with respect to the others that won't be covered by that benefit.

I do think we need to rebalance, as Dr. Crawford said, world pricing. We can't continue to

pay such an obscene premium compared to the rest of the world for research and development. And we're grateful for the cutting edge medicines we have in America. I don't think we should object to paying a premium, but it should be a reasonable premium compared to the rest of the world, not the wide gulf that we're seeing. And as we attempt over the long haul to rebalance world pricing and trade negotiations, or through market forces or otherwise, I would hope that the benefit of that rebalancing would accumulate to the American consumer in some form. And so I think tied to Dr. Crawford's suggestion would be some device or expectation that we would experience some price relief, or at least our prices would go up less slowly than they otherwise would have under a different scenario. But simply rebalancing world prices and allowing that to not benefit the American consumer in some predictable fashion isn't real progress.

And then lastly, I would say we need to be as government smart purchasers. In Minnesota as one example, if you add up all of government, township, city, county, intermediate levels of government, or state colleges and university, our University of Minnesota, all of our state employees, all of the people who are on publicly

assisted health care programs in Minnesota, we purchase something like 60 percent of all the healthcare in the entire state as government broadly. If we bring that purchasing power to bear in the marketplace, not through price controls but as smart purchasers, we can have a significant effect on the marketplace if that's bundled. And so I'm hopeful that our government would revisit things like that prohibition and bulk discounts in the Medicare program.

MR. CONCANNON: Yes, just where Governor Pawlenty left off, I think the single most important thing we could do to help secure better pricing would be to strike the prohibition and the recently enacted Medicare legislation in which paradoxically in a $500 billion spend over a 10 year period, the HHS or the Secretary is prohibited from negotiating better prices. I can't imagine how to explain that to anybody in terms of a rational policy, so that would be, to me, a mightily important step forward.

I can reflect the fact that this concerns us at the state level because in the Medicaid program, and I speak as a Medicaid administrator, nearly half of the Medicaid drug spend in the United States can be accounted for by the so-called dual eligibles, people are both

Medicare and Medicaid eligible. Those costs are going to transfer over to the Medicare bill, and then the states are going to be in the so-called "Claw Back" provision, are going to pay that back, are not going to have access to those resources. But I can tell you as a state person, I'm concerned that absent ?? and with that directive, the Secretary of the Department not to use its purchasing power to secure better pricing, I'm concerned it's going to have an inflationary effect on prescription drug costs. I have very little faith that the pharmaceutical, the PBM industry is going to secure better prices than the government could. And we know the historic lack of transparency in that industry, we've had a step forward in the last couple of weeks with a court settlement that the Attorneys General secured on our behalf, but I still find it a very murky part of the world to try to secure good price information. So I think a major step forward would be strike that prohibition before 2006, and tell the Secretary to use to gather the best minds in the federal government to secure better pricing for Americans.

SURGEON GENERAL CARMONA: Thank you. Yes, Governor.

GOV. HOEVEN: Admiral, if I may, I

can't hardly think of a case where world markets have been opened up, and you haven't had reduction in price.

SURGEON GENERAL CARMONA: Thank you, sir. Mr. Sachdev, a question?

MR. SACHDEV: Yes, Governors. And I want to echo the sentiments of the other panel members in thanking you for being here to help us in achieving our mandate. We were given a very difficult mandate by the Secretary, and that's one that he was given by Congress to look at a series of questions, including safety, liability, impact on innovation related to importation, and to report back to Congress on what we found.

In doing that as part of the task force, we've had several of these listening sessions and heard from a lot of witnesses on different aspects of this, and so we'll be working to pull that together. But I think one of the things I wanted to ask you all about, particularly the Governors, Governor Pawlenty and Governor Hoeven, who already have some experience with your state websites that have been set up, that are linked to Canadian websites, relates to some of the concerns that we've heard, or questions we've heard from other witnesses about the practice of pharmacy in Canada, and how we, if we were to look at a

system for importation, would interface with that practice.

In particular, I think you've heard FDA raise concerns about the fact that they don't really regulate the practice of pharmacy, and really don't have access, and the states generally don't have access to Canadian pharmacies. But, in fact, in Canada we've had witnesses testify who are Canadian pharmacy regulators, including last week we had the Canadian pharmacy regulators from Manitoba, and from Quebec come forward and provide testimony, along with the Canadian Pharmacy Regulator Group, raising some concerns about importation and their ability to assure safety for products that are exported from Canada from their pharmacies.

Similarly, Health Canada has gone on record and said that under their laws they focus their resources on products that licensed Canadian pharmacists are providing to Canadian citizens. And they have a law that's similar to ours related to exports that would direct them to spend less time on products that are intended to be exported to the United States, that imported, then given to their own citizens. That's why I think it's very important that both in Minnesota and North Dakota, in the programs that you've set up with your

websites, that you focus on sending your - in particular in Minnesota - sending your regulators to Canada to look at the Canadian websites.

I know that when you did that, Governor Pawlenty in particular, you found that about 70 percent of the websites had deficiencies, and I think it's important that you chose not to link to those websites.

I'd like both Governor Hoeven, and Pawlenty, and anyone else, any other panel members to comment on this. One of the issues we're interested in is how, if importation is legalized, would we assure the source is protected; in particular, in the event that there was a dispensing error in Canada, how to make sure that ?? or that there are other major deficiencies with Canadian pharmacies, that we would assure that U.S. citizens would have both recourse, but also be protected from those types of problems.

GOV. PAWLENTY: Thank you. I might just one quick aside, and that is when we sometimes have this discussion with our foreign counterparts about this issue, and we suggest, Dr. Crawford, that they're not paying their fair share, one of the things they say is well, why do you allow that non-medically helpful advertising, and how much does that affect your pricing - just to share that

retort with you that we do get from a number of our foreign friends.

As to your question, sir, I think Minnesota's experience was again, we stipulate and everyone readily acknowledges there is all kinds of junk out there, and so one of the great powers and responsibilities that we have as government is we have the ability, I would say the responsibility and the opportunity to sort through all of that, and set up criteria, set up credentials that we want people to follow, expect to follow and then design a recourse if it's not followed. And so the premise in Minnesota was we would use our resources and expertise as a government to go there, to try to set up parameters and criteria that we had with respect to safety expectations, and have those individuals sign a contract that we believe is legally enforceable, although there's lots of folks say well, there's just no way you can have a relationship with the Canadian government or a Canadian pharmacy, and what recourse do we have?

Well, what recourse do you have any time you have an international business relationship? I'm stupefied by the fact that we can't ?? are we really saying we can't design a commercial relationship, or a government relationship with Canada that is not legally

enforceable? I don't ?? I used to practice law. I don't any more, but last I checked, there are ways to do that. There are ways to have appropriate consequences in place, and safeguards in place, so I don't think it's a question of can we. I think the question is do we want to, and how much does it cost? But there's all sorts of criteria we put into our program. You know again, not prescriptions of first use, have to be maintenance medicines. You could have blister packs, you could have dose appropriate amounts, you could have any list of requirements that you want, that you'd expect - in fact, we already know about with respect to American pharmaceutical practice, pharmacy practice, apply those to our Canadian counterparts along with some distribution expectations, and then set up a legal arrangement that is enforceable with recourse.

I don't think it's hard - I shouldn't say it's not hard to do, but it's doable. It is certainly doable. We have complex international relations with entities regulated and otherwise around the world all the time every day, and now when it comes to pharmacies in Canada, we're like oh, how could we possibly do that? How could we possibly enforce those arrangements? It defies what we know about business practice in every other

walk of life.

GOV. HOEVEN: We took a lot of the same steps. Matter of fact, I sent the head of our Department of Human Services and also Duane Houdek, who is here with me today from my staff, along with Governor Pawlenty when they went up and looked at pharmacies in Canada, so we did that exploratory work in the front end.

Second, we picked pharmacies that are not only licensed by the Province of Manitoba, but certified by CIPA, Canadian International Pharmacy Association, which we believe to be a very strong designation. Then we have certifications and requirements in the agreement that do provide restrictions as far as what the pharmacies can deliver to North Dakota citizens that use the site and order the drugs. So again, all of those things can be done, and they can be done by the federal government, we believe very well. And again, that's why I recommended a relationship or a working relationship between FDA and Health Canada, that we think could put this system in place very effectively.

Even if there are certain exceptions that need to be excluded for further work, or because there are concerns, fine. You can certainly do that. The reality is we're doing this

now with Canada on all kind of food products right now. Think of all the food products that we have that are consumed by our people that come into our country from Canada on a regular basis, and we've certainly found a way to manage that and do it safely and effectively.

MR. SACHDEV: Just one follow-up. Again, I want to be clear because we've had this question come up at several of these task force meetings. In the event that one of your citizens of your state was harmed by a dispensing error from a Canadian pharmacy that was linked to your state website, what is the state's position, what would the state do to assist that citizen in achieving recourse from the Canadian pharmacy?

GOV. PAWLENTY: Fortunately, we have not had that experience in Minnesota, and the pharmacies do attempt to some level of disclaimer of responsibility, and the state also has put a disclaimer in, so there is an element of risk, as there are with most things in life, which is precisely why it would be extremely helpful if the federal government would weigh in and create, either through treaty or through regulation, or through contract, a relationship that was not only ?? has integrity from a safety standpoint, but also has an enforceability and recourse to it. And I

think you, not you personally but the federal government has the ability to construct that if you want to. But as to Minnesota's current experience, there is risk. We don't believe the pharmacies are unsafe or the product is unsafe, but in terms of recourse, there are disclaimers both by the state and by the Canadian pharmacies that they may not be responsible under certain conditions, but you could help with that if you want to.

GOV. HOEVEN: We've done the best due diligence that we can. We tried to put the safety features in place, as well. Like I say, certain limitations, certifications that we require from them as to what drugs they can deliver for somebody accessing mail order pharmacy through the website.

You know the reality is, you can go on Google, or you can go on almost any search engine, Yahoo or any search engine you can think of, just go on there and see how many Canadian pharmacies you can access, internet pharmacies, that haven't been checked out by somebody in the United States. So you've got all these search engines out there right now that are available to people. And last year again, on the order of a million people ordered a billion dollars worth of drugs from Canada.

It just makes sense for us to get the federal government, to get FDA involved to set up criteria which will enable us to do this safety and well. And that's why we think, again, it's so important you move forward now.

GOV. PAWLENTY: What we offer is better than nothing. It's a lot better, frankly, but it's happening. It's happening in uncontrolled and unregulated ways. We have brought the power of Minnesota government to bring some assurance of safety and credibility to the program that we have. You could take it to the next level.

MR. SACHDEV: One final question. As I said, I think it's very important in the programs that you have set up that you did the initial work to go to Canada to assess the pharmacies that you link to on your websites that are ?? for the ones that the state is referring its citizens to. Those initial inspections were important, but I want to ask, have you guys done or do you intend to do any follow-up with those pharmacies or any ?? or have you done any follow-up with additional pharmacies that you may be considering adding?

GOV. PAWLENTY: Yes, we have ?? we don't want to pre-announce the visits, but we will be doing and have planned follow-up visits and inspections. We will be shortly announcing some

additional pharmacies. And I'll also tell you in anticipation of the absent federal government action, the pharmaceutical industry choking-off supply to Canada, we do need to explore other countries, and so we're at least in the beginning stages of that, as well.

GOV. HOEVEN: What I would add to that is remember I described in my testimony how our website is structured. Our first option is to take them to therapeutic alternatives, lower-cost, name brand generics through their local pharmacist. That's option one. Option two is what we call Prescription Connection, which is the discounted programs that pharmaceutical companies will provide to lower income individuals. And then we say okay, now third - here are these pharmacies that we've evaluated that is a third option for you. So again, we're trying to work within the framework we have as best we can, but we've got to get help from you at this point to move forward, and that's what we're asking for.

SURGEON GENERAL CARMONA: Governors, Mr. Concannon, thank you all so much for enlightening us. As you know, we've all said we have a very tough job here, but without your input, we wouldn't be able to move this issue forward. So once again from all of us, from Secretary Thompson,

thank you so much for being here with us.

We'll take a short break now while we switch over the tables, and then we'll reconvene. Thank you.

(Whereupon, the proceedings in the above-entitled matter went off the record at 11:38 a.m. and went back on the record at 11:50 a.m.)

SURGEON GENERAL CARMONA: Ladies and gentlemen, welcome back. We'd like to begin the second panel now. Our first speaker will be Mr. John Hurson, of the National Conference of State Legislators. Thank you, sir.

MR. HURSON: Thank you very much. My name is John Hurson. I am actually President-Elect of the National Conference of State Legislatures, and will take over the organization at their annual meeting this July. I'm also a delegate in the State of Maryland, and happy to say that I think you're actually sitting in my legislative district as we meet here today. I'm also Chairman of the Health and Government Operations Committee in the House of Delegates, which considers all these healthcare issues that do go through our chamber.

The work of this task force is extremely important, and I appreciate the opportunity to share a few thoughts with you today. And I am speaking on behalf of the National

Conference of State Legislatures. And while the conference does not currently have a policy on drug reimportation, we are working on one at our annual meeting this summer. And legislatures across the country are actually dealing with this issue and have been dealing with it in the current sessions, and in sessions that have already concluded.

In the 2004 legislative sessions, almost half the states, 21 states have dealt with bills or resolutions dealing with drug reimportation. Two states did pass resolutions, and I can tell you that a third state, our State of Maryland, would have passed it if they had had one more minute in the Senate session. It literally died on the last day of session at the very end, and the bill was actually on the Senate board ready to take a vote, but we just didn't have the time. So it would have passed in our state, as well.

This is because, and you know this, prescription drugs are playing an increasingly critical role in the healthcare of our citizens. Our constituents are finding it increasing difficult to afford the medications prescribed by physicians, and as states, we are searching for answers, but are coming up short in trying to provide low-cost prescription alternatives for them.

State legislatures have experienced and continue to experience unprecedented budget problems, and the genie is really out of the bottle. Our constituents are going to Canada, Mexico, and to the internet to buy affordable prescription drugs.

The Just Say No policy or message regarding drug importation is not resonating with the public. Many of our constituents, generally law abiding citizens, are crossing the borders to obtain these drugs. They're concerned about breaking the law, but they're equally concerned about going without needed prescriptions. We are concerned about the criminalization of drug reimportation, and the effect it may have on individuals with limited options.

The current federal policy on drug reimportation is confusing, at best. State legislatures would find it helpful if the Food and Drug Administration would clarify its personal use policy.

I think it's fair to say that we don't believe that drug reimportation is the goal. Affordable, accessible prescription drugs is the goal. Drug reimportation is merely a means to that end. NCSL shares your concerns about safety and quality. We are particularly concerned about

creating a policy that would encourage seniors and others with lower or fixed incomes to purchase prescription drugs in a way that may ultimately risk their health and safety. That's why the work of this task force is so critical. The task force must be prepared to lay out its findings in a clear and concise way so that policymakers can use this information to make important decision regarding the role of drug reimportation in our future.

Ultimately, if it is determined that drug reimportation is not the right approach, I hope Congress will make it a priority to explore ways to increase the number of individuals with health insurance, thereby increasing access to prescription drug coverage, increasing the affordability of prescription drugs.

Of course, NCSL wishes you success in this important endeavor, and we will be available to be of assistance to you in any way that we possibly can. And I'd be happy to answer any questions.

SURGEON GENERAL CARMONA: Thank you, sir. Our next speaker, Mr. Kurt Knickrehm from the Council of State Governments. Thank you, sir.

MR. KNICKREHM: Thank you very much, Surgeon General Carmona and members of the task force. I greatly appreciate the opportunity to be

here, and frankly thank you guys for your diligence in this effort. This is a very important topic.

My name is Kurt Knickrehm. I'm the Director of the Department of Human Services in Arkansas, which is an umbrella of the Social Services Agency, but I'm here today on behalf of the Council for the State Governments, as I serve as the Vice-Chair of the Health Task Force.

The Council of State Governments represents, of course, a diverse group of the three branches of government. The main mission of the Council of State Governments is really to focus on future and tracking of trends that come about, and then try to identify solutions for states.

Clearly, globalization is one those important trends that we see that's out there. Prescription drugs, of course, are just a component of that whole entire globalization issue.

We all know that the real reason that we're here is frankly because consumers know that drugs are cheaper in other countries. With easy access to online pharmacies, consumers are increasingly taking this route to obtain their prescriptions. For most of our vulnerable citizens, this isn't just an economic issue, it's also a health issue. They too either have to find lower cost drugs across the border, or they're

going to have to do without some lifesaving medicines. The Medicare Modernization Act, of course, will be a huge step forward in helping many of those constituents who face this type of dilemma. Others, however, without access to drug coverage will still have to buy drugs from outside the United States.

In Arkansas, we have about 400,000 folks who are uninsured at the moment. They are the working uninsured, and they still continue to be price-sensitive shoppers. In this regard though, it is not enough for the federal government simply to say don't buy prescription drugs outside of the United States. This path tends to ignore that forces of globalization that we talked about, as well as consumer preferences, and the use of technology.

The federal government needs to work with states, we believe at Council of State Governments, to help consumers be informed of the issues and the risks that are involved with internationalization of prescription drugs. There is, of course, a wide diversity of opinion in state government on the wisdom and feasibility of allowing and supporting drug importation from Canada or any other source. There is, however, near unanimous agreement among those states of the

underlying issue, and that is the rising healthcare costs. Those are outpacing our ability to keep up with, and threatens state's ability to provide some of the basic services.

Prescription drugs are just one part of that overall cost issue, but they're the fastest growing component of our healthcare budget. They represent an increasing portion of that healthcare dollar, especially in Medicaid. My agency, which oversees the Medicaid program, our prescription drug costs are growing about 17 percent a year. This is simply not sustainable in our current environment.

Thus, I encourage the President, Secretary Thompson, and other leaders at the federal level to continue to support state efforts to control the cost of prescription drug costs. For too long, states have had to work around federal government rules and regulations that hamper many of these market reform efforts. Drug importation is but one example of the many ways, or many things that states are doing.

States do applaud the recent approval of multi-state Medicaid waiver on prescription drug purchasing pools between Michigan, Vermont, New Hampshire, Alaska and Nevada. This is an innovative market-based approach to dealing with

this issue.

Similarly, as we heard a little earlier in the first panel, pursuing lower drug costs, no one wants to damage the remarkable and innovative new treatments that have emerged in the American healthcare system. Thus, states support the federal government's efforts to keep other countries, and to get other countries to help pay their fair share of the research and development costs for prescription drugs. To be realistic though, this is very much a long-term approach.

In closing, the caution from the Council of State Governments is to be very wary of putting forward any recommendations that will hamper state efforts and state innovation. Rising healthcare costs are devastating the financial future of families, seniors, and states. States must have the flexibility to continue to address these critical issues. I thank you for your time.

SURGEON GENERAL CARMONA: Thank you, sir. Our next speaker, Mr. Steven Rowe, National Association of Attorneys General. Thank you, sir.

MR. ROWE: Thank you, Admiral Carmona and members of the task force on drug importation. I want to thank you for inviting the National Association of Attorneys General to present information to you today. I appear before you in

my capacity as Attorney General for the State of Maine, as a member of the National Association of Attorneys General, NAG, and as a Co-Chair of NAG's pharmaceutical pricing task force.

I just want to put a disclaimer out here. While I know that many of my fellow State Attorneys General share my views regarding drug importation, I want to make clear that I'm not presenting testimony on behalf of the entire NAG membership today, nor am I presenting testimony on behalf of all members of NAG's pharmaceutical pricing task force.

State Attorneys General are responsible for protecting the public and enforcing the laws of our states. We advise various state agencies with respect to compliance with both state and federal laws. We also advise various state licensing boards, such as pharmacy boards and medical boards. And during the past few years, we have also been advising state legislatures and executive agencies regarding legislation designed to increase the affordability of, and access to prescription drugs for our citizens. And the State of Maine has been particularly active in this regard, as some of you may know.

I know that you're aware of ?? I just heard the governor speak, and Commissioner

Concannon, and I know you're aware that a number of Congressional, and state, and municipal governmental websites provide information designed to assist consumers with purchasing prescription drugs from Canadian pharmacies. And there are a lot of Congressional websites that also have that information.

I know you're also aware of the municipal and the state health plans that are attempting to implement prescription drug purchasing programs utilizing drugs imported from Canada, and these actions by governmental officials appear to directly contradict the FDA's official position that importation is illegal. Similarly, the actual experience of millions of Americans who have safely imported prescription drugs from Canadian pharmacies appears to directly contradict the FDA's repeated warnings that importation poses a threat to the safety of Americans.

As a law enforcement officer and a public safety official, I feel conflicted. I want you to know that. On the one hand, I do not want to encourage citizens to violate federal law. On the other hand, however, for many the only way to access health sustaining and life sustaining prescription drugs is to apparently violate federal laws.

Due to the high prices in the State of Maine, thousands of our citizens have been importing prescriptions drugs from Canadian pharmacies over the past few years. A number of these individuals have looked me squarely in the eye time and again and told me that purchasing from Canadian pharmacies was the only way they could have afforded the drugs that their physicians prescribed. And these were primarily maintenance drugs for chronic conditions like arthritis, diabetes, hypertension, heart disease, elevated cholesterol, and the majority were brand name drugs.

And you heard Commissioner Concannon talk about his experience in Maine. I have yet to hear about any injury from imports or any dispensing errors that were made by Canadian pharmacies dispensing to Maine residents.

The differentials in cost in the United States and Canada are substantial. Citizens in this country, as you've heard time and again I'm sure, pay about 30 to 75 or 80 percent more than Canadians do for the very same drugs. And on a recent bus trip to St. Steven, New Brunswick, 19 Maine seniors collectively saved almost $20,000 for a six month supply of drugs. And this is typical of the experiences of other Maine citizens who have

purchased drugs from Canadian pharmacies either in person, through the mail, or over the internet.

And I use a phrase - I say that the horse is out of the barn, the genie is out of the bottle. And what we need to do is to provide some guidance to citizens, a safe harbor, if you will. And I know that's what you're looking to do.

For a growing number of people in the State of Maine, the choice is either to purchase drugs from a Canadian pharmacy, or do without, and the consequences of electing that do without option often involve worsening health, eventual institutionalization in a hospital or long-term care facility, or eventually death. And these consequences also mean an increased cost to the state, a cost that could have been avoided had the individual stayed healthy and stayed in their home, and stayed on drug maintenance. So I'm not exaggerating to make a political point. I'm stating fact as I know it, based on my experience in our state.

And I continue to be dumbfounded by the FDA officials' intransigent attitude toward importation. Like these federal officials, I care greatly about consumer safety. I certainly want to ensure that citizens in my state access drugs that are safe. However, I believe that procedures

presently exist to ensure that consumers could be protected from unsafe drugs. I mean, I think they are protected in many cases. I'm going to share some information with you, and I'll try to go quickly.

Twenty Attorneys General - you have this letter - twenty Attorneys General recently described such a procedure in a letter to Secretary Thompson. It involves allowing the states to be appointed as licensed wholesalers or to contract with licensed wholesalers for the importation of FDA approved prescription drugs from Canada. The licensed wholesalers could contract directly with licensed Canadian pharmacies, which would then be required to meet safety standards set by the Health Departments of the individual states. And all prescription drug shipments would be made directly to the states. The states would work with Health Canada and the FDA, both of whom, as you know, have systems to ensure that safety and quality of prescription drugs.

They would inspect the Canadian pharmacies and exchange drug plan inspection information. We have the capabilities, I believe, to do that. All drugs would be manufactured in FDA approved facilities and imported into the United States from Canada in their original packaging.

All drugs would be tracked using advanced anti-counterfeiting technology, such as radio frequency identification, chemical markers and bar codes. And in addition, steps would be taken to ensure that the FDA's tracking system works in conjunction with Canada's own comprehensive labeling system, which includes the issuance of a unique drug identification number for all prescription drugs that are commercially sold within Canada.

I just want to emphasize that states are sovereign entities, and we negotiate billions of dollars worth of medical goods and services for our state agencies and health plans. Our pharmacy boards already regulate pharmacists and prescription drug wholesalers, and in some states we administer our own prescription drug discount programs, as you know.

With the assistance of the FDA, I am certain that we could work with Canadian authorities to develop a process for the safe importation of prescription drugs. And I want to follow-up on something the governor has covered, because please note that I have emphasized Canada here, because I believe we should start with Canada, and later expand the program to other countries.

I'm aware that the Canadian market is

small compared to the United States, and that Canadian importation is not the long-term answer to provide sustained price relief for consumers in this country. In fact, I don't think importation in general is a long-term answer, and I believe you agree with that. However, relief is urgently needed, and importation will provide some of that relief now, not in the future but now.

Let me say, I also support the efforts ongoing in the federal Congress that are intended to provide prescription drug price relief by allowing importation from Canada with certain restrictions. I particularly support the bill that's been mentioned today, the Pharmaceutical Market Access and Drug Safety Act of 2004, which is sponsored by Senators Dorgan, Snow, Kennedy, Daschle, and McCain, among others. This bill includes specific measures to ensure the overall safety and integrity of imported drugs by requiring that a chain of custody be maintained and inspected. It requires that wholesalers meet high standards, including detailed recordkeeping, labeling, and tracking requirements. And it requires frequent FDA inspections of pharmacies and wholesalers, and it employs the latest in anti-counterfeiting technologies.

In closing, let me say that I

appreciate the complexity of the product safety issues that you're dealing with, including the risk of counterfeiting, contamination, and mislabeling. I also appreciate the politically charged atmosphere that surrounds the drug reimportation or importation issue. I believe the key to whether you will be able to recommend to Secretary Thompson that prescription drug importation can be conducted safely is whether you want to or not.

I come here today in the hope that you, indeed, do want to. And after hearing your today, I believe that you do want to. And I want to just tell you that we in the State of Maine are ready to work with you to find a solution.

I mentioned about the horse being out of the barn. It's tough. Consumers are looking for some direction, and that's why folks are going out and putting up on the websites, governmental organizations, but they're doing it with some trepidation because the FDA keeps saying it's a violation of federal law. We know we can do it safely. We need to explain to consumers the best way to do it safely.

Anyway, I very much appreciate you inviting me here today. Thank you.

SURGEON GENERAL CARMONA: Thank you, sir. Our next speaker, Mr. Jim Frogue, with the

American Legislative Exchange Council. Thank you, sir.

MR. FROGUE: Good morning. My name is James Frogue, and I'm Director of the Health and Human Services Task Force at the American Legislative Exchange Council. ALEC is a 30-year old organization made up of 2,400 state legislators from all 50 states. We are the largest bipartisan organization of individual state legislators in the country. Our membership also includes approximately 300 private sector members, and we receive no taxpayer dollars.

As Task Force Director, it is my job to work with our legislators and private sector members to maximize patient empowerment. ALEC is divided up into 10 task forces, other task forces address issues such as education, tax and fiscal policy, the environment, technology, to name a few. Each task force can have a maximum of three legislators per state. Our task forces meet three times each year to discuss the issues of greatest importance to our legislative members.

At each meeting, task force members consider model legislation that if passed, goes on to become available to all ALEC members to use as they see fit in their respective states.

We just returned from Austin, Texas

where last weekend we completed our annual spring task force summit. The HHS Task Force passed the attached resolution, which you have attached to my testimony, by a vote of 52-0. The purpose of the resolution was to recognize the dangers inherent in importation, acknowledge the good work, but limited scope of the FDA, and place ALEC clearly on record as opposed to the illegal importation of non-FDA approved prescription drugs due to concerns about safety.

An announcement from the FDA on September 29th of last year found that nearly 90 percent of mail parcels arriving from foreign countries that had prescription drugs, contained medications that violated American drug safety laws. For some elements of this debate, to minimize concerns over safety is simply irresponsible in light of this single study.

Beyond the very legitimate risks associated with importation is the question of whether or not it would actually be effective in lowering drug prices for American consumers. In order for importation from Canada, for example, to place significant downward pressure on American retail prices, there would have to be a tidal wave of product coming from north of the border. This simply cannot and will not happen.

Canada represents approximately 2 percent of the global prescription drug market, with the U.S. around 50. Under no circumstances would a market as small as Canada set the broad prices for a market 25 times its size. This is due to the simple fact that drug manufacturers can control the number of their pills on the market, and they will not indefinitely sell Manitoba wholesalers exponentially more product than is needed for citizens of Manitoba.

The rights of patent holders are clearly enshrined in both American and international law in trade agreements. Title 35 U.S. Code Section 271 states that "whoever without authority makes, uses, offers to sell, or sells any patented invention within the United States, or imports into the United States any patented invention during the term of the patent infringes that patent." Article 1709 of NAFTA, and Articles 27 and 28 of the World Trade Organization's Trade-Related Intellectual Property Agreement also secure the rights of patent holders.

This being the case, manufacturers of patented medications have domestic and international legal recourse against middlemen who seek to violate the terms of private licensing agreements. To suggest as some have both here and

abroad that drug makers should be sanctioned, forced to sell their product on unfavorable terms, or be subject to compulsory licensing is a full frontal assault on intellectual property rights, the kind that would be unthinkable if the subject were movies or software.

Just last week, Congressional Budget Office released a six-page paper entitled, "Would Prescription Drug Importation Reduce U.S. Drug Spending". Their analysis concluded that HR-24-27 introduced by Representatives Gil Gutnecht of Minnesota and Ron Emanuel of Illinois that would permit importation from a broad range of industrialized countries, would lower 10-year drug sending by 1 percent. They attributed this negligible savings largely to the ability of patent holders to control the amount of their product on the market. It is up to policymakers to decide if a 1 percent savings is worth a very significant risk.

As a result of reduced supplies in Canada, Canadian pharmacies and, therefore, patients are beginning to experience drug shortages. Health Canada's Assistant Deputy Minister Diane Gorman stated that she, "regards this as a very serious matter". Michelle Fontaine, Vice President of the Coalition for Manitoba

Pharmacy, recently experienced a shortage of drugs to treat cancer and high blood pressure.

Suffice it to say, Canadian politicians are not going to sit idly by when medications needed by their constituents are being sent to America. Chalk up this impediment as another major reason why American consumers are highly unlikely to see widespread Canadian prices in this country.

Let us keep in mind exactly who are the bulk of Americans traveling out of the country, or going on line to get foreign drugs. They are mostly low income, uninsured, ineligible for Medicare. They are not members of Congress, or 9 million federal employees, their dependents and retirees who get to choose from a wide array of competing, comprehensive private insurance plans, all of which have excellent drug coverage.

Indeed, it was the Federal Employees Health Benefits plan that should have been the model for Medicare reform last year. It has been around longer than Medicare. It is tried and tested, and has provided more comprehensive services to its beneficiaries.

Thank you for your attention, and I look forward to any questions.

SURGEON GENERAL CARMONA: Thank you all panel members. Task force, questions? Dr.

Crawford.

DR. CRAWFORD: Yes. Thank you very much. Mr. Rowe, I wanted to first compliment you on your conscientious program, and intention to try to get safe and affordable drugs on the market in the U.S. And I recognize that are not only conscientious but have thought about this a great deal. There are a couple of things on behalf of FDA I'd like to respond to.

One is, you said something like we were proceeding as if this was illegal, the importation of drugs from Canada. The fact is, is that they are illegal. The second thing is that you said that we were being intransigent, and that may or may not be. That may be our middle name, but we do it for the reason of safety and protection of the American people.

If, in fact, there is, God forbid an adverse event or a series of adverse events from products imported from Canada, keep in mind that the same Diane Gorman that was just quoted from Canada, who is in effect my counterpart, has said that she has no legal authority to control these drugs. We have no legal authority to deal with them, except to declare them illegal. But if something goes wrong, like using these kinds of products as an agent of terrorism or something like

that, you're looking at who would be blamed for that. So we have to proceed very cautiously, indeed.

I appreciate what you're trying to do, but let's be sure of the facts; and that is that FDA has a charge to keep in this regard, and we're trying to do it.

MR. ROWE: Can I just say something? I understand that, and FDA has said that it's illegal, but we're not going to enforce the law with respect to some of the things going on now. My point is that there are citizens that feel conflicted. People want to abide by the law, but they can't do it. We have people in my state who don't qualify for any public subsidies, and who don't have enough money to pay their rent, to buy their food, and to pay for their six or seven prescriptions. So they asked their doctor, can your prioritize these for me? They split pills. You know the story. You've heard this before.

I've been around the state, and when you talk about risk, I mean, there are dispensing errors in this country, there has been contamination, there has been counterfeiting in this country. I think it's a risk analysis, and you make it as safe as you can. But I'm telling you now, and you know this, people are dying

because they can't afford the medications that would keep them alive. People are going into nursing homes rather than remain independent and healthy because they can't afford the medications that would keep them independent and healthy.

I mean, it's happening in my state and I know these people. And so, you know, it's not a perfect world. And I think it's a risk analysis, but let's reduce that risk as much as we can. And I think we can save some lives that way. I'm not talking ?? I'm in agreement, but I think we know what we're talking about, so I appreciate your comments.

DR. CRAWFORD: With permission, General.

SURGEON GENERAL CARMONA: Please.

DR. CRAWFORD: Thank you for that. The purpose of Surgeon General Carmona's task force here is to come to some sort of solution, as you well know, and that's why you're here, and that's why we're here. So thanks.

SURGEON GENERAL CARMONA: Yes. Thank you so much. Other comments. Yes, Ms. Willis.

MS. WILLIS: Yes, for Mr. Rowe again. You mentioned and suggested that perhaps the U.S. government could work out an arrangement with Health Canada. Considering the information that

Mr. Frogue provided and comments by Dr. Crawford, do you know if Health Canada or the Canadian government is interested in working out such an arrangement with the United States?

MR. ROWE: I would expect today they might be skeptical based on what's going on with the pressure by the pharmaceutical industry in Canada, but I think if we were to put a plan in place, I think you would see a change of attitudes. I have not talked with officials with that organization, so what I'm putting forward is, I believe, a process that I'm asking you to look at. But a lot of the fear that's going on in Canada is created by the pharmaceutical companies, and there are some investigations going on with respect to anti-trust and collusion. But it's a concerted effort, a calculated effort to put fear in the minds of Canadians, in the minds of consumers, in the minds of pharmacists, in the minds of wholesalers, and in the minds, I believe, of Health Canada about what will happen if we should open up importation and make it legal. So I think you can't look at today. I think we have to look at this is going to require some dialogue, and I wouldn't have put this forward if I didn't think it would work.

There are 20 Ags that signed on to

this. We've talked a lot. I know people who have dealt with Health Canada. I personally have not.

SURGEON GENERAL CARMONA: Mr. Reilly.

MR. REILLY: This is again for Mr. Rowe. I appreciate some specific proposals you have in here. We hear a lot of testimony on either side of the issue, and don't always get specific suggestions. I did have a question, because it seems, if I heard your testimony correctly, that it wouldn't necessarily be the federal governments working with Health Canada, it would be individual states who would be licensed to import drugs, and they would work on individual state arrangements. Maybe you can describe a little more how that would work, and would states be the only licensed wholesalers for importation?

MR. ROWE: I think it could vary by state, Mr. Reilly, but the idea would be, and the proposal would be that states would be able to be wholesalers or they would license another wholesaler on behalf of the state to work directly with Canadian pharmacies. Both FDA and Health Canada would work with the states, and I mentioned, because that's ensuring the safety and the quality of the drugs, and the inspection of the pharmacies, and exchanging drug plan inspection information. But some individual states might not elect to do

this, but I'm just saying I think states are, as you know, under federalism, we're sovereign governments.

We work with prescription drugs now. We license all of the professionals. We license pharmacists, we license the pharmacies, both in-state and those mail order. Right now most states, as you probably know, DUC cannot license because the state laws would have to be amended to license that out of country pharmacy as a mail-order pharmacy, but I believe we could do that. And once we did that ?? I mean, this is a plan, and we haven't worked it out in minute detail, but I think the framework is there, and I'm just asking you to look at that.

It's a very conservative plan, I believe, when you look at the safeguards that I propose today, and many of these are contained in the bill that's in the U.S. senate.

SURGEON GENERAL CARMONA: You've got another one? Yes, Mr. Reilly. Please.

MR. REILLY: To follow-up on that, so if some states chose not to participate, and once some states do import drugs, would there be some prohibition in selling to those states - you know, imported drugs in those states, would that be a mechanism our regulatory procedure would have to

work out?

MR. ROWE: Yes. I would expect all states would participate. The procedure that I put forward is not favoring border states. It would be something that would benefit all states, regardless of geographic location.

SURGEON GENERAL CARMONA: Okay. Mr. Sachdev.

MR. SACHDEV: This is a question that follows up on the question that Mr. Reilly just asked, and it actually is framed to any one of, or all members of the panel. And I again thank you all for being here to help us do our job. It's a tough job. We have a broad mandate in the form of the questions that Congress raised to the Secretary, and he asked to opine on for him.

In particular, one set of questions that he asked us to comment on that we've been looking at, and asking all of the panels about, relates to the direct and indirect costs, including potential increased liability costs associated with importation if it were legalized more broadly. Specifically, you heard I think this morning's testimony where the governors who have already established websites that link to Canadian pharmacies have disclaimed any liability related to purchases, as related to the state's costs for any

problems resulting from the purchase of those products from Canada.

In a system where you legalize this, where the state is, in fact, a player in that because they regulate the pharmacies that are licensed to practice business in the states, have any of you, and in discussions in state legislatures, in discussions at the state government level, have there been ?? is there additional information that can inform us about the potential or estimated costs associated with increased liability, increased insurance that may go along with any proposal to legalize importation?

MR. HURSON: I can't tell you specifically any discussions that have gone on in specific legislatures. What I would point out is that without guidance from the federal government as to how to do this, you're going to get not 50 different solutions, you're going to get hundreds of different approaches, and all kinds of different regulatory schemes about how to avoid liability, how to create insurance programs. You know, last year there were 21 states that considered various ways of doing this. Next year there'll be 35 states, unless something is done. So I think the point is, is that while there's probably been a lot of discussion in state legislative settings about

how to go about doing this and what the implications are, you don't get uniform testimony, you don't get uniform concepts about how to deal with the liability questions. You're going to get very, very different approaches.

Usually that's something we like at the state level, but in this particular case I think it's safety issues, that the federal government provide direction on how to go about doing this. And we do consider ourselves sovereign states, and do consider our ability to go about doing this one of our rights, so it's important, I think, that we do get guidance, because you are going to get different approaches to this. I'm not sure that answers your question, but I think it's important to state that there isn't going to be a uniform approach on liability or insurance, or anything else until we get guidance from the federal government.

MR. KNICKREHM: I would just echo that there have been a lot of discussions about the liability piece, as well as the physician liability. If a physician writes the script here and it goes off to ?? and something changes in the reimportation side, where does that liability rise, so those discussions are in place. But like my colleague, I believe that most of those are kind of

a risk and reward piece; same thing in terms of the mechanisms that a state would have to put into place to try to regulate some of these things. There's an additional cost associated with that.

Again, it just comes down to the affordability piece. Part of the comment about numerous ways to approach this, that's exactly what's going on. The states are approaching this in very many ways. Part of that becomes the challenge that you guys have to face on how to give some of the guidance so that we don't have 50 different approaches to this piece.

MR. FROGUE: Well, thank you for that question. I think that's a very, very important question, and the answer I think anyone can give is, you just don't know what the liability could be. That's still up in the air. But I think what is important is that there are certain members of the trial bar that would certainly go after deep pockets. And if counties or states were promoting this activity and someone got injured, it's reasonable to think that the creativity and persistence of certain lawyers would lead to lawsuits against states and counties. What they would result in, it's hard to tell. But would they result, I think it's very plausible, yes.

MR. ROWE: If I could just ??

SURGEON GENERAL CARMONA: Please, sir. Go ahead.

MR. ROWE: I don't have a dollar figure, but I would just say that whatever ?? I would be happy to undertake an analysis, but whatever you came up with, I would compare that with the expenditures that states are making now with their ever-escalating Medicaid budget, with prescription drugs increasing at the highest level of increase of all medical expenses, and to look at the long-term care facility bills that states are paying because people have to spend down to a point where they had to go into ?? either qualify for Medicaid, go into a long-term care facility. So my point is, there are lots of expenses now I think that states are incurring that would be reduced dramatically should we find a way to allow importation that would reduce the cost of prescription drugs to our citizens. So I think you might see ?? I don't know exactly what that would be, but I think you would see a substantial decrease in state expenditures on the other side.

MR. SACHDEV: I would simply ask each of you, and I appreciate the comments from each of you, if you ?? after you leave here, and we have a docket open until June 1st, if you have additional information in this area - this is an area that we

are looking for information. The CBO, the Congressional Budget Office, just recently noted that there would be less than ?? very, very small, less than 1 percent savings over 10 years. We've had a witness testify at a session two weeks ago, who made clear that in the parallel trading system in Europe, where there is parallel trading occurring amongst countries in drugs, what they were finding was that there was very little cost passed on to the consumer. And, in fact, much, if not all, the vast majority of this potential savings from importation in parallel trading situations were being collected by the wholesalers and the pharmacists, and not being passed to the insurers, or to the consumer. That type of analysis at the state level would be very useful to the task force.

SURGEON GENERAL CARMONA: Thank you. Yes, Mr. Azar.

MR. AZAR: Mr. Frogue, I wanted to see if you could help me with something that ?? Attorney General Rowe in his remarks raised, I think, a very important point that has not had much discussion here; that he is aware of individuals who have died or have to be institutionalized because they could afford to buy drugs at the Canadian price, but couldn't afford the

differential of the American market price. And I wanted to see, as someone who has testified against importation, how do you respond to that? How should policymakers who are trying to address this issue face that question? A very, very important one, obviously.

MR. FROGUE: Absolutely. A couple of things. First of all, this debate is not about brick and mortar Canadian pharmacies. Mr. Rowe's state, people in Maine and Vermont, and Minnesota, they're lucky in that most of them can actually physically go to Canada, buy the drugs at a pharmacy, and they are safe. Governor Pawlenty has often said show me the dead Canadians. I mean, it's a fair comment.

The issue is more about the trans-shipped drugs that Health Canada does not control, and drugs bought online. That's where I think the significant potential for problem is far higher.

In this little booklet that I passed out that I put together with a colleague of mine, we list a series of anecdotes from around the world and Canada, here in the United States, where we talk about the problems in supply. And the most, I think, egregious one is the one from September, where the FDA found that 90 percent of the mail parcels received, 90 percent of the drugs were

drugs that didn't meet FDA standards. So I think that's something, and it's very easy to fake a drug and not know about it right away.

I mean, an analysis, when we import food, there hasn't been real problems there. Well, it's kind of hard to fake a banana, and there's not a lot of money in that. But it's very easy to fake a pill. And I think when we talk about this issue, it is important to recognize that Canadian brick and mortar pharmacies that people go physically visit are not the problem. It's more the online, .CA does not mean it actually is in Canada. It could be anywhere, and that's I think where more of the problem is, and what should be the focus.

MR. AZAR: What if you were to come up with a system, though, that then dealt with importation only from the brick and mortar Canadian pharmacies and distribution systems, and somehow avoid the trans-shipment issue?

MR. FROGUE: Then you get to the issue of where does the supply come from? And I think that's ?? when we talk about safety, that's a very important issue. But ultimately, the issue that makes importation a false promise is where is the supply going to come from? You can't force manufacturers to sell Manitoba 30 times more product than they actually need. Could you do

that? Maybe you could, but does that mean there's going to be so much supply there that every consumer in the United States can get Canadian prices? Absolutely not.

MR. AZAR: I just ?? General Rowe, I wanted to mention, and I, obviously, don't know these individuals and their circumstances. And I don't know what the State of Maine does here, but just to take off on something I think Dr. McClellan would say if he were here. There might be some programs, and the states, I think, can play a very important role in educating consumers, patients about a lot of programs that people just aren't aware of out there, and whether these individuals would qualify for them or not, obviously, I wouldn't know, but there are an increasing number of pharmaceutical company programs for low-income individuals, and several of them have already announced that under the new prescription drug discount card benefit, when an individual qualifies for the $600 a year transitional assistance, if they run out of that money, they will actually give their drugs for free to those individuals automatically if they need them. And then some, and I know that I was just looking through Mr. Frogue's brochure - there is a list in here of some other discount programs that a lot of people just

may not be educated about, that they might qualify for. And then obviously Medicaid enrollment, people who could qualify for that. And then, hopefully the drug discount card which I'm sure all the governors are going to be out there trying to educate Medicare beneficiaries about possible savings, and certainly trying to get everybody who is eligible enrolled in the transitional assistance to get that $600.

And then something that Dr. McClellan has talked a lot about is generic substitution and alternative drugs, really trying to educate consumers about the options that are out there that they may not know about, that are dramatically lower cost, but therapeutically the same. So I don't know what Maine is doing there, and I obviously don't know the situation of these individuals, but the more states can do to help us with ?? we're trying also, but the more we can do to educate people who are in that kind of a situation, I think the better it will be also.

MR. ROWE: That's a good comment. We are. I think we're doing all of the above. We're working hard, and the challenge right now is to educate people about our low cost drug programs for the elderly and the Medicare prescription drug benefit, and how they dovetail, and how it can be

most beneficial to you. But all the things you said, one of the issues is a complexity of all this stuff. Wouldn't it be nice if you could pay less for a drug, than trying to find out all the subsidies that might be available to help you pay a higher price for a drug, and that's what we have right now for a lot of folks. And it's very complex. And when you get old, I live with my 80-year old mother-in-law and my 87-year old father-in-law, and with age comes a difficulty sometimes dealing with a lot of complexity. And right now, it's very complex. And what I'm suggesting, if we work with this, it's going to be less complex. We're talking about reducing the price of the drug, as opposed to giving subsidies to help you pay for it.

But what you said, Mr. Azar, and I think if you look at our DHS website, my website, you'll see we a lot of information to try to help consumers. Unfortunately, a lot of seniors don't access the internet either. That's not the be all, end all for communications, as you know.

SURGEON GENERAL CARMONA: Task force, other questions or comments. Yes.

MS. HARDIN: I just want to reinforce what was said before about soliciting information on the liability issues. Mr. Rowe, I'm going to

pick on you because you are an Attorney General, and have obviously worked with Attorney Generals around the country on this issue.

Aside from just trying to define the numbers on a possible liability problem, any information that you or your group can share with us about thinking through the actual substantive liability issues that might arise, particularly you may have already looked at liability issues that may arise if you participate as a wholesaler or a distributor and importation. That would be very helpful.

MR. ROWE: I will do that. Thank you. We'll get something to you.

SURGEON GENERAL CARMONA: Yes.

MR. KNICKREHM: If may just add one comment to that; one of the things that I think we have to look at across this too, is not just the ?? it is that uninsured population too, at the same time. In our state, as I've mentioned, we have about 400,000 who are all working. The number one reason for bankruptcy in our state are healthcare costs, it's all health care related, and that is systematic across the country too, so there's other social costs associated with this, not only the liability and the infrastructure costs are all part of this.

SURGEON GENERAL CARMONA: Thank you. Dr. O'Grady.

DR. O'GRADY: Hi. Just to not pick on poor Attorney General Rowe, I'd like to ask the other panel members some questions. Mr. Frogue brought up the CBO estimates that they've put out, and that is a little haunting to me, in terms of, as I said to the other panel, having come from a border area where I understood the price differentials, and the Canadians come over to get lower prices on whatever commodities we have. I'm a little concerned by the implications of the CBO logic. I understand what they're saying there, and that if you really did kind of fully implement, if you really took some of these steps, you're in a situation where the U.S. market is at least 10 times the size of the Canadian market. Certainly, that's our population, and that we would go through great efforts, and then find out that when we were all done with that, we have very little to show. Because I do believe that the bottom line here is an ocean of how you affect prices.

We don't talk about Canadian gasoline that much any more. You know, I mean it's just not that much difference. Why would go to the effort? And so I guess my concern, and I'd like you to discuss a little bit if you have some thoughts on

this, is like I say, I'm a little haunted that we go to this effort, and five, ten years from now we turn around and we say those kinds of ?? unfortunately in this case, we're absolutely right, and we're looking at a minimal price difference in terms of just that 87-year old grandfather or father-in-law kind of face when they get down to the CVS.

Any thoughts on that one, of that kind of economy of scale. It's one thing when folks are going across and going to Montreal, or Toronto. It's something different if we are talking about a full implementation.

MR. HURSON: Let me just say that I think that the way to look at this is not, or at least the way I look at it, 7,000 legislators who are part of NCSL look at is we're facing individuals in our constituencies who are looking at media reports that say that it's half the cost for the drugs that we're taking. Why can't we, as policymakers, figure out a way that they can purchase these drugs in Canada? And we get the pressure to figure out some solution there.

Is some kind of national program of reimportation the right way to go? Probably not, but we're reacting to the political pressure of our senior citizens who are saying their aunts, and

uncles, and sisters, and brothers who live in Vermont and New Hampshire, able to get the drugs for half of what they have to pay.

I don't think reimportation, I think probably most legislators don't see reimportation as sort of the solution to the problem, even on a massive scale. You've got to find a different way to deal with the high cost of now one of the most important components of healthcare for seniors. I think Congress made an attempt to do that. I think there are some problems with the bill, and those will be worked out. But it's not going to solve the problem overnight. We're looking for that one solution, that one thing, Canadian reimportation for our citizens, doesn't matter what CBO says to my legislators. You know, I've got the pressure from my constituents to do something to help them get the Canadian drugs. That's the bottom line.

MR. KNICKREHM: Dr. O'Grady, I'm in complete agreement that this discussion is really about price. Reimportation is just one of the many strategies that have come out of states. Overall, increasing pharmaceutical cost is not necessarily a bad thing if they're being spent in the right areas, and are actually decreasing hospitalizations, and a whole host of things. So just that, in and of itself, is not a bad thing.

But states have done things with preferred drug lists, states have done things in disease management areas, states of done things - evidence-based medicine approaches to the pharmaceutical side at the same time, all of which are trying to get our arms around the drug pricing, and frankly, the entire economy in the healthcare world.

We are still an interesting component on how we fund research in this country, and it really is about price. This, I think, is just one small strategy. It is not the ultimate strategy. There's certainly not a silver bullet to it, but it is one of many that I think keep continuing to come back to how do we control the price of healthcare and deliver that healthcare to all citizens in this country.

MR. FROGUE: Delegate Hurson certainly makes a good point. We hear that exact line from our legislators, too. It is very difficult to respond to that, why is it half the price in Canada? Why can't I get that too? But keep in mind that that's for uncovered retail drugs, low-income, uninsured seniors, uncovered retail drugs. It is far, far, far better to be a United States Congressman or federal worker and get your drugs here in Rockville, than buy them retail uncovered in Canada. There is no coverage in Canada. You

pay retail. Yes, it's cheaper, but it's much better to have a $10 or $20 co-pay here, much safer drugs, no risk in that area, and far less money out-of-pocket if you have the appropriate coverage.

That makes it difficult for Delegate Hurson because it's not as much his issue, as it is a federal issue. Again, the Federal Employees Health Benefits Program is older than Medicare. It works very well. That's what Congress and the administration should have done last time around in December. Instead, we got a tiny little pilot program that starts in 2010 that's for about 1 percent of the population. It should have been for everyone immediately. It works. This is not some tried untested theoretical model.

DR. O'GRADY: Can I ask one more question?

SURGEON GENERAL CARMONA: Please, go ahead, Dr. O'Grady.

DR. O'GRADY: Mr. Frogue, just in terms of the way the logic as you've laid it out here, I guess there is one just follow-up in terms of your testimony and whatnot, because your testimony very much focuses on the safety and the concerns about safety, and I think there's certainly many of us, well all of us are very concerned about the safety aspect of it. But if for some reason we wave the

magic wand and the safety concerns go away, are there other things that are still problematic to you, or is that really the nub of the issue?

MR. FROGUE: Absolutely, and I think it was just touched on, in five or ten years, as the CBO said, you're not going to see much of a price differential at all, simply because it's about supply. You can't have reduced supply and demand. You can't have reduced price here, if there's no supply to meet the demand. I mean, it's really that simple.

Safety is an issue, of course, and something we should all be concerned about. And we can go back and forth on whether or not it's safe, and you can make good points on both sides of that argument. That's why we opposed, or our legislators decided to oppose importation because of the safety issue, but beyond that, the supply issue is an even bigger one. You can't promise Canadian prices because there's just not going to be supply of Canadian drugs at those prices.

MR. ROWE: Can I just add to that?

SURGEON GENERAL CARMONA: Yes, sir. Go ahead.

MR. ROWE: I just want to say to Dr. O'Grady's question, I will look at the CBO analysis. I'm not as familiar ?? I'm not very

familiar with that at all, I'll admit. I need to go and look at that carefully and share it with some of my peers, and try to bring back while the docket is open some information. Also on the liability issue, look at that. But I want to agree that I think that the Medicare prescription drug benefit we gave up the biggest thing that we had, which was our purchasing power, our clout in the marketplace. And that's really what we need to get back, in my opinion. Maybe that's a little political statement, but I think importation is not the long-term fix, clearly not. It's a shame that we're here talking about importation today, I mean, but the rebalancing of world prices that you heard Governor Pawlenty talk about, it has to happen. And also, the expenditures.

The unique thing, and it finally came back to me about what we're talking about, this product. It's not a pair of shoes where you can go out and get a $20 pair, a $50 pair, a $100 pair, a $200 pair, and the $50 pair will keep you warm and dry. Sometimes there's one drug and it costs 200 bucks, and it's a necessity of life item. This is a unique product we're talking about, and we're paying 30 to 70 percent more. And it's just what's wrong with this picture?

I know you know this, but don't think

?? I think I speak for all of us. None of us think that importation is the silver bullet here, but it's a way to get where we need to go. And I think for some people, it's going to help them an awful lot. It's helping people in my state already. The folks in Kansas and Oklahoma probably aren't getting the benefit that some people in my state are getting because of where we're located. Thank you.

SURGEON GENERAL CARMONA: Thank you, sir. Mr. Hurson, I thank you for maybe pointing out the obvious, what we might describe as the elephant in the room as it relates to this issue, that we've heard it repeatedly, especially from elected officials that they're confronted with a constituency that wants something done, a constituency that often isn't aware of the complexities of all of the issues that we are dealing with here, nor do they want to be aware of the complexities. They just want the medication that they need. And it's been an extraordinarily difficult issue for us to deal with in terms of what we call health literacy in our first few meetings, is how do we adequately inform the public as to the complexity of this? And we just can't discount those complex issues, because they have long and short-term implications economically, and

safety-wise. And so engaging the American public in this in further depth than just a sound byte or a headline is the difficulty here.

You know, we're driven by the science, what the best practices are, and our reports will reflect that. And unfortunately, it is the elected officials then that will then get to decide based on our input what needs to get done. But we are still confronted with a very difficult issue that we're all struggling with, is how to engage the American public, those who vote to be better informed citizens as to the complexity of this issue. And I'm not sure that, as much as we've done with the media and we've done with our own leadership, we've done the best job yet. And a lot of it is, quite frankly, some of the apathy from the American public when we attempt to discuss these issues, that they don't want to have that discussion. So any of you who can help us and shed a light on that, but the themes that seem to be emerging here a fairly consistent, from experts, from law enforcement, to our elected officials, to all of you, that nobody seems to look at importation as the solution, but rather a band aid, that we have to do something. And we're tasked with figuring out is that the right something to do? What evidence would support it, and if we do

it, at what cost? And notwithstanding the liability when we talk about bringing in an importation program and each state doing one, or states banding together, the issue of regulation, the issue of oversight, who does it - and notwithstanding the liability, there's a huge cost also. And at some point, that cost benefit analysis becomes extraordinarily important because to some who have written on this academically, it's simple a matter of cost shifting. You're really not saving any money, you're just moving the cost someplace else.

So if there are no more questions, I would just like to thank you all. It's been really informative for us. I really appreciate your input. We'll go ahead and switch over to the other panel now.

(Whereupon, the proceedings in the above-entitled matter went off the record at 12:46 p.m. and went back on the record at 12:50 p.m.)

SURGEON GENERAL CARMONA: The finish line is in sight. I think we've got our last panel here. I thank you, gentlemen, for your patience. We're running just a little bit behind, but as you know, the time frames on these are just estimated because of the fact that sometimes we get into some very important discussions that we don't want to

curtail. And all of us had agreed early on that when the discussion is fruitful and giving us important information that we'll continue even though it may impose some restrictions on our deadlines.

Our first speaker in panel number 3, Mr. Thomas Ryan from CVS. Sir, thank you.

MR. RYAN: Thank you, Mr. Chairman, members of the task force. I applaud you on your persistence in this tough problem that we face as a country.

By way of background, I'm Chairman and President of CVS/Pharmacy. After completing our acquisition that we recently announced, we'll have over 5,000 stores in 36 states. We'll dispense about 14 percent of all the prescriptions in the country, and we'll purchase about $16 billion of drugs, largest purchaser in the U.S. In addition to that, we also have a Pharmacy Benefit Management Company with about 30 million live, so we are living this challenge every day with the three and a half million customers that come in our stores day in and day out.

While many in our industry believe the importation issue is a fundamentally flawed concept and oppose it, I come with a slightly different view. While there are many programs out there

alluded to earlier by Mr. Azar around manufacturers' programs, the Together Card, the Pfizer Sharecard, the government programs, the Medicare program, retail programs, the consumer doesn't really understand the programs. We spend a lot of time trying to educate the consumer on those programs. But having said that, it still doesn't solve the issue. It doesn't treat the underlying condition, if you will. It only relieves some of the symptoms. And the condition I'm referring to is the way prices are set around the world. And I think we've heard a little bit about that today, but to give you an example, I mentioned that we're the largest purchaser of drugs.

A consumer in the United States can buy a drug in Canada at retail for anywhere from 14 to 40 percent less than we can purchase it, not sell it, than we can purchase that particular drug. I think the issue around having safety and accessibility are important issues, but these arguments miss the core. The existing underlying global pricing model cannot be sustained.

I am not advocating price controls. It's a fact that a Ford Taurus, a Dell laptop, or a bottle of Tylenol all cost more in the U.S. than they do in Canada. That's the market working, not arbitrary government price controls. Global

pricing is a complex problem with an either simple explanation or solution. But this much I believe is clear, no industry can permanently sustain a pricing system where the cost of the product arbitrarily varies that much, so much between a country, and pharmaceuticals are certainly no exception. We must find a common ground. So I put forth two basic principles.

One, I believe the federal government and pharmaceutical companies must move to a global pricing system. You've heard it before, you've heard it from other people testifying. We cannot support all the R&D in the world. I would suggest that the U.S. Trade Representative begin to lead this dialogue and establish a more market-based pricing system with our partners.

The recent U.S.-Australia Free Trade Agreement is a notable advance on this front. The administration must elevate this to the highest level. And this is not just about seniors or the uninsured, Mr. Chairman. I think this is about all payers. Prescription drugs are costing all payers, private companies, as well as the government. Now fixing these disparities in price will not be a simple task, as you alluded to, and will not be quick. This brings me to my second principle.

While the process moves forward, many

Americans need help today. It is this help that CVS/Pharmacy calls on the administration and Congress to quickly establish a means for customers to legally and safely import prescription drugs. It may be a stop-gap measure, it may only last three or four years, but it's a solution that needs to happen. To do otherwise would ignore the millions of Americans who are playing prescription roulette as we speak.

Today there are well over 100 internet pharmacies sending medications into the U.S. from Canada alone. And as you've heard this morning from the governors, there are states and cities setting up programs for the uninsured, or directly to their employees.

Mr. Chairman, I believe that if CVS/Pharmacy tried to import drugs for our customers, the federal and state authorities would shut us down within the hour. It's not acceptable to let this trade practice happen in the shadows.

Now I recognize there are many potential issues around problems with importation, which drugs do we import because they don't have uniform standards, how do we ensure adequate supply, which was alluded to earlier, how do we determine who the intellectual property rights work? These are just a few of the issues we need

to tackle. But I believe opening up a domestic distribution system to additional sources of individuals will increase the potential for counterfeit and adulterated product.

Therefore, I believe the lowest risk is bulk importation, designated and approved foreign entities, designated and approved licensed wholesalers, and designated and approved U.S. pharmacies. Such a system would give you a clear drug pedigree, a chain of custody, the use of appropriate anti-counterfeiting technologies, and we would charge adequate fees for these exporters to have federal oversight and inspections.

In contrast, legalizing direct importation for consumers would involve millions of packages, from hundreds of sources. The resources needed to ensure the safety would be massive, compared to the safeguards.

To conclude, we all know this is not an academic exercise, and I applaud you for what you're going through. Millions of Americans have already opted to import drugs because they can't afford not to. We owe it to them to face this issue head-on and not look the other way. If importation is made legal and safe, CVS/Pharmacy will play an active role. But in the long term, the answer must be fair and equitable trade

practices.

We cannot allow millions of our fellow citizens to go without life sustaining medications due to arbitrary international trade practices. We don't do it for sugar, we don't do it for rice, and we don't do it for corn, we shouldn't do it for life-saving medications. And I guess you've heard a lot about this from others, but the difference is now you're hearing it from someone who is the largest purchaser of pharmaceuticals, and the largest dispenser of pharmaceuticals in the U.S. Thank you.

SURGEON GENERAL CARMONA: Thank you, sir. Our next speaker, Mr. Thomas Paul, Ovations United Health Group.

MR. PAUL: Thank you, Mr. Chairman and task force for inviting United Health Group to participate in today's meeting. We're pleased to provide a perspective from a payer, or a health purchaser perspective in regard to drug importation.

Ovations is a company within United Health Group that focuses in on Americans 50 and older, so we focus in on a senior population. But included in the broader business, United Health Group, we provide healthcare services to over 55 million Americans, which makes us the largest

provider of health and well-being services in the country today.

United Health Group is committed to finding solutions to making healthcare coverage affordable for all Americans. We believe that senior Americans are most affected by some of the decisions that are going on today, and throughout the country in regard to healthcare, and especially to prescription drugs.

Many of the older Americans that we work with under our Medicare programs and Medicaid programs are living on fixed incomes, have limited prescription drug coverage, and have more chronic healthcare conditions than younger Americans, causing them to take more prescription drugs. So it's easy to understand from our perspective why people are seeking alternatives other than the current American systems to purchase their prescription drugs, and are forcing them to go beyond the border or to international internet pharmacies.

In regard to importation, I think our thoughts are consistent with many of the issues that have been stated previously today, and with respect to time, what we probably wanted to do is emphasize some of the issues that may not have been addressed at this point. And they really focus in

on our primary perspective in being a healthcare provider, and that's in the continuity and effectiveness and efficiency in the care that's provided.

There's been a lot of discussion today, and I imagine from what you've heard in the past in regard to safety, but one area that we would like to highlight is in regard to the continuity of care. And Tom Ryan, as a pharmacy provider, talked a little bit about safety, but I wanted to kind of expand on something that he may not have said, and that's the value of what happens when an individual has continuity of where they receive their prescription drugs.

Today part of our concern with importation has to do with the fact that as individuals cross the border and go to pharmacies in order to purchase some of their medications, but go to their local pharmacy for other medications, that what may end up happening is a disconnection in what we would call a single profile system.

Within our benefit coverage, and our benefit provision today, we connect all of the pharmacies within our network so that if they go to a CVS/Pharmacy in California and then travel to a CVS/Pharmacy in New York, there's consistent drug utilization reviews that are taking place on our

members' profiles, so the CVS pharmacist has access to that connection, that continuity of care.

By causing the separation and allowing individuals to go to a Canadian pharmacy, you all of sudden now disconnect that profile, and that becomes for us a concern in the continuity of care. In doing so, what we would recommend, that if importation is something that is pursued, that mechanisms be put in place, such as like Mr. Ryan was saying, is that current U.S. systems for the processing of claims or the delivery of pharmaceutical care within the U.S. allow for that continuity, so that we can connect those pharmacies into the current drug utilization systems.

The second piece that we'd like to emphasize was a question that was brought up during the first panel today, and that has to do with if importation is not the answer for affordability, what are the other answers that are available? And again, United focuses on it from a continuity and quality of care, and would like to emphasize our commitment to improve the research on comparative efficacy of drugs that are released today.

In fact, we believe that in focusing on comparative efficacy and causing that to be a standard within the U.S., that it could have just as great of an impact as importation of drugs from

other countries, as well. We believe that in providing comparative efficacy it provides physicians, pharmacists, consumers enough information in order for them to make informed decisions about their purchasing decisions, so that they are not ?? that they are selected medications or treatment regimens that are based on the most cost-effective therapies that will bring the greatest outcome.

In addition, we believe that it will drive more appropriate research to focus in on innovative therapies rather than those therapies that expand the marketplace without expanding efficacy, quality, or general outcomes.

So with those two statements said, as kind of in addition to what has already been said today, we do believe that all Americans should have access to prescription drugs that are appropriate to treat their medical conditions, and that we need to find ways to ensure that Americans, particularly older Americans, can afford those needed medications. And we strongly support further steps to lower cost for senior Americans. Thank you.

SURGEON GENERAL CARMONA: Thank you. Our next speaker and final speaker, Mr. Allen Dunehew. Sir, thank you for being with us.

MR. DUNEHEW: Thank you, Attorney

General. I'd like to thank all of you for the invitation to come here and participate in this effort. It's commendable, and for your work on this long process.

My name is Allen Dunehew. I'm Vice President of Pharmacy for Amerinet. I'm a registered pharmacist, and I've practiced pharmacy for many years in various provider settings, including in border towns in Northern Maine. I have also served on the Vermont Board of Pharmacy, as well, in past lives.

Currently in my position at Amerinet, I'm responsible for the strategic direction of the pharmacy program, including contracting clinical pharmacy services, marketing strategies related to pharmacy and development programs that provide value to all members. We are a proud member of the Health Industry Group Purchasing Association, or what we refer to as HIGPA, and I'm here on behalf of them today to represent HIGPA, and the members.

HIGPA is a trade association for health care group, purchasing organizations or GPOs, and represents over 170 healthcare supply chain organizations, such as Amerinet. HIGPA's trading partner members include many of the world's leading manufacturers of healthcare products, including pharmaceuticals, as well as distributors,

wholesalers, and related suppliers.

My comments for this will apply primarily to the importation, or the issues surrounding importation by healthcare providers other than in the ambulatory setting, which is what most of today really speaks to. HIGPA's GPO members aggregate the purchasing power of the healthcare members and negotiate discounted prices for practically everything that providers need to buy, and you've heard some comments this morning about the value of aggregating purchasing volume.

According to a study conducted by a former principal analyst at the Congressional Budget Office, hospitals save patients over $30 billion each year by purchasing products through a GPO contract, so there is some value associated with that.

In regards to HIGPA, I serve as the association's Chair of the Pharmacy Working Group, which was created about two years ago, primarily at that time with a focus on drug product shortages. And we've been involved in a number of task forces in that area, as well as other various pharmacy issues.

One of the working group's most recent efforts was in response to concerns and questions raised by pharmacists concerning drug shortages,

product integrity, and a primary and secondary sourcing and distribution channels, which all play into this issue of importation potentially, and the unique challenges presented in ensuring the safety of patient care products.

The unique role of GPOs in the marketplace provides us with an ideal opportunity to help our provider members deal with drug shortages. WE recently published a white paper entitled, "Integrity of the Pharmaceutical Supply Chain Product Sourcing for Patient Safety", and we have submitted that for the record for your review. It was unanimously adopted by HIGPA's Board of Directors, and released to the public in February, 2004.

It's important to note that when a healthcare provider is in urgent need of a product that is unavailable in the routine distribution channel, an alternative source must be accessed. To take just a moment to define terms, secondary distributors or secondary distribution channel is described in this context as movement of products from an authorized distributor or manufacturer to a source other than the manufacturer, and intermediary distributor, or the like, which could come into play as you talk about these importation issues. Those products are then sold to a provider

for the dispensing to the end customer, or directly to an end customer.

Following our highlights of our suggestions for healthcare providers to consider as they contemplate accessing this marketplace, we strongly suggest that they require of alternatives sources, provide them as a minimum at least the following, the pedigree back to the previous source. The preferred is back to the point of origin to show true product integrity, and we all know that that's a challenge today. Certify that it's not a diverted product, certify that actions by the alternative source will not alter any original manufacturer warranties or guarantees, which is an important issue. And certify that the product has been stored and handled consistent with labeling requirements, as we've heard about earlier.

We also suggest that they consider development of lists of key pharmaceutical products that will not be purchased from products other than the direct manufacturer or authorized distribution channel because of their potential for counterfeiting and safety issues, storage issues, whatever.

In this context, the HIGPA Pharmacy Working Group also reviewed the issues surrounding

the drug importation by healthcare providers, and patients. The members of the working group believe that many of the same safeguards as I just described also apply to the importation of pharmaceuticals.

In addition, the following issues have been identified; the integrity of an imported product may be questionable, and there is no current pedigree process available to validate the integrity of that product, at least an effective process. Due to the lack of this available system and technology to facilitate the assignment and tracking of serial numbers for individual packages, there is no secure method to separate imported stock from stock obtained through primary distribution channels, unless that labeling is different, so that's important to think about, how this product would appear on the pharmacist's shelf. There's also no currently available technology used to validate that an imported or reimported product was stored according to USP standards, as we've discussed.

Our working group outlined the minimum safeguards that we feel are critical to have in place prior to importation. They include an electronic pedigree to provide secure track and trace of product at the individual package level

throughout the supply chain, regardless of its source; development by the FDA of acceptable and efficient regulations on reimportation and importation to ensure integrity of the imported product. And we separate those two issues out, reimportation and importation because they are very different; development of technology that tracks storage conditions, validates, conforms to the USP standards, assurance that entities in other countries which export products to the U.S. market are regulated appropriately using the same standards as required of the U.S. supply chain, and have the authority to sell products in the U.S. without compromising warranties or intellectual property rights.

The guidelines state that pursing importation as a cost-saving strategy without implementation of safeguards places an undue risk on patient care in its current initiatives in place to improve patient's care and safety.

Going forward, HIGPA believes providers should look to the position of the Food and Drug Administration as a final rule on importation and reimportation, and let that position serve as a key indicator of its acceptability. We have encouraged our member providers to consider these issues as they make decisions regarding the sources of

products.

It is recommended that providers who are interested in accessing pharmaceuticals from outside the U.S. distribution system should first become involved in advocating for the implementation of systems that facilitate electronic pedigree to ensure the integrity, and become educated about all those vast issues that come to play in that. Anything short of this may be construed as placing financial considerations above patient care and safety.

We recognize that healthcare costs are escalating and there is a constant need to relieve cost pressures. This is what GPOs strive to do everyday. Unfortunately, without the proper safeguards, importation provides more risk than the potential savings may be worth. At the end of the day, we as the primary contractors for the healthcare supply chain must come down squarely on the side of what is in the best interest of patients.

I encourage you to break down this issue of counterfeiting into its many diverse and complex subsections as you start to contemplate these issues, because you may find that one part of it is okay, but others may provide too many risks.

I commend Health and Human Services Secretary Thompson, Surgeon General Carmona, and the members of the task force for focusing attention on such an important part of the healthcare supply chain, and thank you for the opportunity to contribute to this effort.

SURGEON GENERAL CARMONA: Thank you, sir. Members of the task force, questions for our panel members. Dr. O'Grady, and then we'll go to Mr. Reilly.

DR. O'GRADY: Mr. Ryan, certainly this is a bold proposal you've put on the table here. And I certainly want to commend you and appreciate that you're sort of taking the time to sort of lay out specifics how things would go. And I just want to ask you a few kind of follow-up in terms of getting a feel for exactly how it might work. And with the understanding that nobody works out all the details of how these things would work right off the bat. But in terms of ?? you talk about a number of things having to do with sort of licensed and approved entities on both sides of the border. Did you have a feeling for or thoughts on exactly who would do that and how that might work?

MR. RYAN: Well, first, doctor, your point about we spent a lot of time coming to this decision, and because it flies in the face, you

know, it's essentially illegal, and yet our consumers are out there, our patients are out there going to pharmacies, and coming into our stores and talking to our pharmacist saying what are we going to do about this? So I think it's an issue that we don't ?? a position we don't take lightly.

The fact of the matter is we believe there's about 3 billion drugs across the markets now, including Europe, Australia, not just Canada. Canada is a piece, the biggest piece. It's the most visible right now, obviously because of the proximity, but we believe it's up to $3 billion. And we see individuals who don't even have a high school diploma setting up shop, opening up a store front, individuals come in. Our concern is the patient, so we have a healthcare system in place, as Tom alluded to earlier. We have a distribution system in place in this country. We have licensed pharmaceutical wholesalers. We have, obviously, 54,000 pharmacies.

The issue would be licensing and inspecting those foreign entities. That's the key. I mean, we don't have all the answers here. There's issues around supply, there's issues around inventory separation, how do you do that? You know, maybe this is a step for the uninsured initially, if you think about it, but at the end of

the day, it can be done. I mean, to think that you're going to have $3 billion worth of drugs coming into Main Street, U.S.A. from hundreds and hundreds of internet pharmacies and be able to monitor that - I mean, Dr. McClellan and I have had one-on-ones on this for a number of periods of time, and my comment to him has always been why not use the system we have in place? Although imperfect, it's a system of checks and balances. We know the U.S. piece of it. Let's put our focus on the foreign piece of it. And it's going to take some monies to step up to it, but I talked a little bit about that around the fee, so difficult ?? easy say, difficult do, but at the end of the day, I think there is an opportunity for us to do it. It can happen.

DR. O'GRADY: Okay. Just a follow-up. So in terms of the way you're conceptualizing this right now, you're saying that you feel that the most ?? if there's some vulnerability, it's this individual sort of transactions going on. So is it this ?? for the most part you'd see this sort of reimportation or importation, or however you want to think about it, is it going to be ?? would it mostly be between wholesalers? Is that the way to conceptualize it?

MR. RYAN: I would think it would be ??

the way we envision it would be from a "certified" exporter to an approved U.S. wholesaler, with all the necessary licensing, storage agreements, insurance liability coverage to a licensed U.S. pharmacy, internet, license to internet pharmacies, Drug Store.com, mail order, retail, but a system that's in place that we have checks and balances on, as opposed to situations that you had in Oklahoma where the FDA actually shut down some of those firms.

DR. O'GRADY: What would CVS' role be in this? Would it sort of act as one of these wholesalers for their own then ??

MR. RYAN: No, no, no. We would be one of the 54,000 pharmacies.

DR. O'GRADY: Okay. Thank you.

SURGEON GENERAL CARMONA: Mr. Reilly.

MR. REILLY: This is also for Mr. Ryan. You had said that if you tried to import and sell drugs from Canada, you'd be shut down very quickly. This is a hypothetical. There were no legal impediments. We've heard a lot of testimony from the governors this morning and from others that going across the border buying drugs from a Canadian pharmacy, they feel perfectly safe. Without these systems in place that you've talked about, would CVS feel comfortable doing business

with a Canadian pharmacy and putting those products on their shelves?

MR. RYAN: Sure. Let's make the assumption that it is legal, so we would do the necessary due diligence and quality controls to ensure that wherever we're importing the drugs from, or obtaining the drugs from would be quality and the type of quality of drugs that you should be importing.

We alluded to it a little bit earlier here that even in our U.S. system, there are still drugs that are out there that are not U.S. approved, that enter our system today, that come from secondary wholesalers, that get pushed out of the country and come back in. We have to monitor that day in and day out, 400 million prescriptions. So the issue for us would be there are retail pharmacies in Canada obtaining drugs. Where are they getting drugs from? They're getting the drugs from Canadian wholesalers. We would go to those Canadian wholesalers and import approved drugs, so I don't think ?? our issue would not be, once again the legality aside, our issue would not be a safety issue. Our issue at the end of the day would probably be a supply issue. Could we, in fact, get the necessary supply?

But I go back to the bigger issue. The

broader issue is, and it's a difficult one that we all have to address as a country. And you have a difficult challenge here. You're dealing with trade practices and health practices, or trade policy and health policy in countries around the world. How do you influence that? But I believe that if you do put some pressure on individual countries and pharmaceutical manufacturers are allowed to raise their prices in other countries to cover their return on capital, return on investment that they're making, I believe you will see pharmaceutical manufacturers in this country begin to lower prices to take share in this country. Now they can't afford to do that, because they need to get the return on their investment, so it's not an easy problem, and it's not a problem that will be solved overnight, but I think it's something that we have to step up to and let other governments know that it's just unacceptable at this point.

SURGEON GENERAL CARMONA: Thank you. Other comments, questions, panel members?

DR. O'GRADY: Can I ask ??

SURGEON GENERAL CARMONA: Please, go ahead, Dr. O'Grady.

DR. O'GRADY: Mr. Paul, you went into a discussion about kind of comparative data and how to ?? what I think of is in the genre of more

prudent consumer, consumerism going on here. But you seem to stop a little short of ?? I mean, you were talking about comparative effectiveness, but I didn't quite get cost effectiveness. Now I assume given that we're talking about price and whatnot, was ?? I just wanted to ask a follow-up. We you also thinking of cost effectiveness there in terms of that, and at kind of what level? I mean, the British government has come under a certain amount of criticism for sort of being somewhat hardline about those sort of things, but what were you guys thinking of in terms of how you might comparative, cost effectiveness, some of these other ideas out there to be a more prudent consumer?

MR. PAUL: Right. Coming from a consumer's standpoint or a pairs perspective, it does get into the comparative efficacy of one drug compared to another, and then what's the cost value if they're not comparable. So today, in the system that we have today what we know is there's a list of drugs that treat cholesterol, and we know that there's a variance in price in each of those. But what we don't always know is how each one of those compares to each other in the effectiveness of reducing cholesterol. So we may be paying $70 for a drug that may be less effective in comparison to a $50 drug. So when you get down to the

comparative research, what you get to is a point where you know that your clinical value and your outcomes value is comparable to the cost value. And we know that at one point that may be skewed, where the cost value may be ?? it can be higher cost for a less effective agent. So in our case, we would use it to help to make benefit determinations or coverage determinations, but be doing it more from a clinical outcomes perspective, rather than a pure cost perspective.

DR. O'GRADY: Now is that data, is that infrastructure in place at this point?

MR. PAUL: There is actually very little comparative data out on prescription drugs today. There is safety and efficacy data that often may compare to a placebo or potentially older therapies, but when you look at comparing new therapies to each other, there's very little data out there, and even less when you look at a senior population, which is where a lot of the emphasis is placed.

DR. O'GRADY: Then do you have to actually make a coverage decision, cover something and then kind of have your own data to then go back after a year or two of coverage and sort of say wait a second, we're paying much more for this, and it seems either no more effective, or less

effective?

MR. PAUL: In essence today, United has kind of adopted a policy of we don't really limit what people have access to, so in our benefit policies, we have open access to prescription drugs. But where we do have variances is again, the level of that benefit determination, and often that level is determined on its effectiveness, or its comparability, or how it ?? what is the general outcome from both a quality and a cost perspective. So as new data comes out, we review it to make sure that the decisions we made previously are still the right decisions.

DR. O'GRADY: Gotcha. So a beneficiary may still be able to have access to that drug, but it may have a higher co-pay than it would have once that data is sort of ?? that determination is made.

MR. PAUL: Exactly.

DR. O'GRADY: Thank you.

SURGEON GENERAL CARMONA: Any other comments, questions? Yes, Mr. Reilly.

MR. REILLY: Both Mr. Ryan and Mr. Dunehew have laid out components of systems that might work to help ensure the safety. This is a two-part question. Any sense at all about what, as a percentage of drug sales or would that cost 2 percent, 3 percent, 5 percent, or any notion at all

about what we might? And I understand if not, because that's not an easy question.

But, Mr. Ryan, you also suggested I think that all or some of these costs be borne by fees on, I think you said exporters?

MR. RYAN: Exporter fees, right.

MR. REILLY: So like Canadian pharmacies.

MR. RYAN: Right. What you do with devices now, there are certain fees that are charged. You could do that with the foreign exporters.

MR. REILLY: And what the cost of this scheme would end up being, should the entire cost be borne by fees, or do you have any view on should the federal government bear the cost directly, which I guess then would be ?? I assume the fees would be passed on in pricing to the consumer, or to purchasers, whereas if it's cost borne, put in the FDA budget, for example, it would be a cost borne by all taxpayers. Do you have any views on ??

MR. RYAN: Well, obviously, the devil is in the detail, and we haven't worked out the whole scheme in the British sense, as it were. I don't think it would cost a lot. There's a whole infrastructure and distribution structure in place.

The situation would be - and I'm over-simplifying it, so I apologize because it's obviously not that easy - but the issue would be once you have the pedigree on the drug, once you understand where the drug is coming from, once you ensure the quality of that exporter, whatever it costs for the U.S. government to do that, FDA, DEA, that cost would be paid for by somebody.

Now let's just put that aside. But once it comes into the system, the wholesalers and the retail pharmacies wouldn't have any additional costs. They'd be just calling on drugs the way we normally call on, so I'm over-simplifying it, but I don't think there would be a lot of costs.

Now the question was alluded to earlier about how much the savings would be, is it material enough? Are we going to go through all of this, and is it really going to save anything? Well, when you think about the largest purchaser in the U.S., CVS, and we can't purchase the drugs for 14 to 40 percent less than they're selling them, there has to be more savings than 2 or 3 percent. There has to be.

Now what the pharmaceutical manufacturers do with pricing is a question to be discussed, but I do think there has to be some savings there.

MR. DUNEHEW: On the system, I think you're referring to RFID that I mentioned, Track and Trace. Right? I work with another association, as well, on some issues, and that is one of them. In my own opinions, this is my own opinion - RFID presents a lot of benefits just beyond Track and Trace, and there are actually pilots that are being developed and put together now to demonstrate that. There are a number of retail pharmacy chains, CVS is one, that's getting involved in a pilot, as well as a few manufacturers who have products that have been subjected to counterfeiting. And in that sense, there are studies underway, but in addition to Track and Trace, that type of a system offers a lot of benefits beyond true efficiency in the supply chain and distribution channel. And it's interesting at a time when the FDA has just published a bar code final rule, and that's going to be enacted.

Again, my own opinion, I think it's conceivable that certainly seven years out maybe, perhaps even before, but there will be a time when RFID tags could potentially replace bar code tags. And so now you build Track and Trace in as part of a system. And that's what I was alluding to a little bit earlier when I talked about developing a system that provides safety and integrity. And

that's probably not an overnight thing.

Now the question is how long can we wait for that, but the price of those systems is dropping as they're becoming more mainstream. They're certainly not there yet, but there are a number of demonstration projects that are put together, so I think that that is a viable alternative or way to introduce safety into the system. It's just it's not going to be here tomorrow.

MR. RYAN: I would just add that we are working - we were the first retail pharmacy to work with the RFID system. And initially they started out about 8 cents apiece, and now they're getting down to about 5 cents apiece, but having said that, that's something we need to do in the U.S. I think that's something we need to do in general, but we have a big challenge right here and now. And I think you can ensure the safety and effectiveness of the drugs that you import without RFID technology coming from your ?? they don't have RFID technologies in Canada. They don't have them in Europe, and they're buying drugs there now, so it would help in the long run, I think in three to four years we should have it.

If world pricing was all the same and we didn't have this issue, we still should have

RFID technology in the U.S. But having said that, I do think we can do it safely and effectively.

SURGEON GENERAL CARMONA: Thank you. Dr. Duke.

DR. DUKE: I'm looking for guidance because of the interaction of two sets of this problem. In your discussion, your testimony, you talked about the bulk purchase. And I do agree with Dr. O'Grady, I think that was a bolden proposal, and it is nice to see a proposal from time to time in this discussion.

I'm trying to put together the three panels of this morning, and I think one of the themes of the previous panels has been the tremendous pressure that folks feel at local and state levels from constituents. And I'm looking at the ?? you've got a systemic solution, which may bring down prices some unknown at this point, and we're going back and forth to the study that Dr. O'Grady mentioned earlier.

On the one hand, that we believe could, after significant investment of energy and effort, and policy and time, produce some savings. On the other side, there's an investment in enforcement resources for FDA to close down the sort of backdoor channel that has not been enforced up to this point. Which then has the FDA arresting

grandma. And I have a little concern around some of ?? constituency issues around how we, as a free society, work that issue too. And I'm seeking guidance here. Believe me, this is a dilemma.

MR. RYAN: I'm seeking guidance too.

DR. DUKE: I know.

MR. RYAN: It's a tough issue. Obviously, it's a politically charged issue, but the way our laws are written, it's illegal. And I just harken back to if CVS with 5,000 stores decided to import drugs and take care of grandma, we'd be shut down. Mark and I have discussed it, and he doesn't have the number of people and the resources to go after it. He's trying to do it. He shut down some in Florida, and some in Tulsa, as I said earlier. But you shut it down, and I'm getting the same drug that my friends in Toronto are getting, you know, and why are you not letting me take it? I know it's a challenge, but that's why I think we need some bold moves, and we can't be working around the fringe. We either have to say we're going to allow imports, or we're going to shut it down. We can't be looking the other way because it's a politically charged football. And I hate to say it, but that's what's happening now. And I understand that, you know, any governor in any state shuts down one of these, he's not very

popular, or she's not very popular. I get it, but at the end of the day, I think it's either legal or it's not. So I'm suggesting a way that I believe we could solve at least probably the uninsured issue, and perhaps the low income seniors issue around a relatively, I don't say simple, but a relatively easy solution.

DR. DUKE: Thank you very much.

MR. RYAN: Maybe not all drugs, by the way. It might be just some drugs. One thing I will say, as a little off to the side, so I'll stop, but each state has their own Medicaid system. And as you know, private insurers allow brand name and generic drugs to be dispensed. And there's also different co-pays for brand to drive the consumer, but you can't do that with Medicaid program. And I think that's something you can fix pretty quickly. There's no difference in co-pay. You are not allowed to have a different co-pay for generic and brands at the state level, which flies in the face of where healthcare is headed, so states have to go through a waiver. And to me, generics - there's no incentive for physicians to write generics on a Medicaid recipient so, therefore, we're just driving the cost up. But that's a small item.

SURGEON GENERAL CARMONA: Other

questions or comments? If not, gentlemen, thank you so much for your time. We really appreciate your input. It's going to help us a great deal in our deliberations. Task Force members, thank you for hanging in there once again, and we'll stand adjourned.

(Whereupon, the proceedings in the above-entitled matter went off the record at 1:32 p.m.)